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Occupational Safety and Health Administration

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OCCUPATIONAL EXPOSURE TO 1,2-DIBROMO-3-CHLOROPROPANE (DBCP)

Proposed Standard, Hearing

[4510-26]

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[29 CFR Part 1910]

[Docket No. H-61]

OCCUPATIONAL EXPOSURE TO 1,2-DIBROMO-3-CHLOROPROPANE (DBCP)

Proposed Standard, Hearing

AGENCY: Occupational Safety and Health Administration, Department of Labor.

ACTION: Proposed standard, notice of hearing.

SUMMARY: This proposed permanent standard on occupational exposure to DBCP is based largely on the evidence that led to the issuance of an Emergency Temporary Standard (ETS) on September 9, 1977, (42 FR 45586). That evidence established that occupational exposure to DBCP presents grave danger from hazards of cancer and sterility as well as other toxic effects. The proposal revises the existing 29 CFR 1910.1044 as established by the ETS by reducing the permissible exposure limits from 10 parts per billion (ppb) time-weighted average (TWA) and 50 ppb as averaged over any 15 minutes during the working day (ceiling) to a TWA of 1 ppb and a ceiling of 10 ppb. In addition, the proposed standard requires employee exposure measurements, engineering controls, personal protective equipment and clothing, employee training, medical surveillance, work practices, regulated areas, change rooms, and recordkeeping. A public hearing on the proposed permanent standard will commence on December 13, 1977. The permanent standard will supersede the existing ETS at the conclusion of the rulemaking.

DATES: Comments and notices of appearance concerning the proposed rule must be received by December 2, 1977; all materials which will be introduced into the hearing record must also be received by December 2, 1977; an informal hearing is scheduled to begin on December 13, 1977.

FOR FURTHER INFORMATION CONTACT:

Ms. Flo Ryer, Director of the Office of Special Standards Programs, Directorate of Health Standards Programs, OSHA, Third Street and Constitution Avenue NW., Room N3663, Washington, D.C. 20210, 202-523-7174.

SUPPLEMENTARY INFORMATION: This is a proposed standard on occupational exposure to DBCP which is issued pursuant to sections 6(b), 6(c), 8(c), and 8(g) of the Occupational Safety and Health Act of 1970 (The Act) (84 Stat. 1593, 1596, 1599, 1600; 29 U.S.C. 655, 657), Secretary of Labor's Order No. 8-76 (41 FR 25059) and Title 29, Code of Federal Regulations (CFR) Part 1911. It proposes to amend Part 1910 of 29 CFR by revising 29 CFR 1910.1044, to provide a permanent standard for the regulation of occupational exposure to DBCP. This standard would apply to all employments in all industries covered by the Act, including "general industry", construction, and maritime, excluding only agriculture. The development of a permanent standard will be conducted under the rulemaking procedures of section 6 (b) of the Act. The agency requests the submission of written comments, data, and arguments from interested persons on all the issues raised in the ETS and proposal, and has scheduled an informal public hearing for the presentation of oral testimony. After the hearing, the Occupational Safety and Health Administration (OSHA) will issue a final standard or decision based on the entire record developed, including written comments and the informal rulemaking hearing.

OSHA seeks public comments, information, and evidence on all the issues raised in the ETS and the proposal, including the following:

1. Whether the proposed provisions would provide adequate worker protection from all health hazards associated with DBCP exposure.

2. Whether DBCP should be considered as posing a carcinogenic risk to humans.

3. Whether the proposed permissible exposure limit of 1 ppb (TWA) and the ceiling level of 10 ppb are sufficiently low to protect workers from any adverse health effects.

4. Whether compliance with the proposed exposure limits would be technologically and economically feasible for all affected industries.

5. Whether the provisions for recordkeeping, methods of compliance, medical surveillance, regulated areas, personal protective equipment, protective clothing, hygiene facilities and practices are appropriate and feasible.

6. Whether there are alternative medical procedures to sperm count and measurement of hormone levels which are equally effective in the detection of sterility and other reproductive effects in male and female workers.

7. What medical procedures, effective in the detection of cancer in its early stages, should be a part of a medical surveillance program.

8. Whether medical removal protection should be provided where, as a result of the medical surveillance program, it is determined that an employee is at an increased risk of material impairment of health from further exposure to DBCP.

9. Whether the provisions for training, posting and labeling are appropriate and fully apprise employees of the hazards of DBCP exposure.

10. What are the environmental and economic impacts of the proposal.

I. Background

DBCP has been used as an agricultural nematocide since 1955. It is a dense yellow or amber liquid with a pungent odor at high temperatures. It has a low vapor pressure (0.8 mm Hg at 20° C) and is slightly soluble in water (1,000 ppm).

DBCP is produced primarily by the bromination of allyl chloride at room temperature, usually a vigorus reaction which requires cooling. DBCP is produced in the United States by Dow Chemical Co. and Shell Chemical Co. The Federal Republic of Germany, Mexico, and Israel also export DBCP to this country. About 12 million pounds of DBCP were consumed in 1972.

DBCP is shipped to formulators who reprocess the chemical into products for consumer use. Formulators may vary the concentration of the chemical in an end product or change its physical state by simple blending and mixing operations. DBCP is formulated into emulsifiable concentrates, liquid concentrates, powder, granules, and solid material. Formulating granular DBCP involves spraying liquid DBCP onto inert granules. The formulation of liquid and emulsified DBCP concentrates can involve the following operations: transferring technical grade DBCP from railroad tank cars to storage tanks, and from the storage tanks to a mixing tank; adding an emulsifier or solvent to the mixing tank; transferring the blended material to a holding tank and then to drums; and also other transferring operations taking place during the packaging of the DBCP materials. About 80 formulators have labels registered with EPA for the approximately 160 products containing DBCP although it is not known how many of the firms are presently engaged in the formulation of DBCP pesticides. The complete distribution chain generally includes the manufacture of technical grade DBCP, transportation to formulator, formulation of DBCP pesticides, distribution of DBCP pesticide and the agricultural consumption of DBCP pesticide.

In 1961, the authors of a research paper, Torkelson et al. recommended that occupational exposure to DBCP be controlled to less than 1 ppm in air. No voluntary Threshold Limit Value or federal regulatory limit was established for occupational exposure to DBCP until the ETS, setting a level of 10 ppb, TWA, was promulgated by OSHA on September 9, 1977. About 2,000 to 3,000 production employees in facilities manufacturing and formulating DBCP have been or may be exposed.

On August 5, 1977, the Oil, Chemical and Atomic Workers (OCAW) union requested that the National Institute for Occupational Safety and Health (NIOSH) conduct a health hazard evaluation at the Occidental Chemical Co. plant.

In a statement to OSHA, Dr. Donald Whorton, University of California at Berkeley, said:

> There were some of the men from the Ag-Chem area at Oxy Chem who had volunteered for sperm analysis. Now the reason that they had done this is that for several years around the lunch table the men noted that they had not been having children since working in that area. Now since a large number of the men are in the child bearing age and have been wanting to have children, this was striking. It remained at the level of an unconfirmed rumor for several years. In the last eight to twelve months there have been two people to file worker's compensation com-

plaints for pesticide poisoning. Among other things they also cited sterility. Now as far as I know, these are isolated cases and no one has ever put it together. The union finally talked some men into volunteering for sperm analysis. Seven of the men went and volunteered. (August 31, 1977, Statement of Dr. Whorton.)

Dr. Whorton had consulted prior to August 5, 1977, with the company and the union and had conducted medical examinations of the affected employees. Medical examinations of a number of additional employees have subsequently been conducted by NIOSH staff in conjunction with Dr. Whorton.

On August 12, 1977, the Occupational Safety and Health Administration in a telegram alerted approximately 80 manufacturers and formulators to the potential hazard of worker exposure to DBCP. On August 23, a guideline document detailing suggested work practices was forwarded to these same affected companies. Although Shell and Dow have temporarily suspended production of DBCP and requested the return of outstanding stocks of the substance, its use in formulating pesticides may still be occurring.

On August 19, 1977, the Director of NIOSH wrote to the major manufacturers of DBCP requesting information to fully evaluate the extent of the hazard posed by exposure to DBCP.

On August 23, 1977, the Oil, Chemical and Atomic Workers International Union President A. F. Grospiron formally requested that the Secretary of Labor take immediate steps to prevent worker exposure to DBCP. Specifically, OCAW requested that worker exposure be limited to one part DBCP per billion parts of air and that a broad testing program to locate incidents of cancer and sterility among workers be established.

In the September 9, 1977 issue of the FEDERAL REGISTER (42 FR 45536), OSHA published an Emergency Temporary Standard (ETS) regulating DBCP exposure in the workplace (29 CFR 1910.-1044). A correction document was published on September 16, 1977 (42 FR 46540).

II. PERTINENT LEGAL AUTHORITY

The primary purpose of the Act is to assure, so far as possible, safe and healthful working conditions for every working man and woman. One means prescribed by Congress to achieve this goal is the authority vested in the Secretary of Labor to set mandatory safety and health standards.

Occupational safety and health standards provide notice of the requisite conduct or exposure level and provide a basis for assuring the existence of safe and healthful workplaces. The Act provides that:

> The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. (Section 6(b)(5).)

Sections 2(b) (5) and (6), 20, 21, 22, and 24 of the Act reflects Congress recognition that conclusive medical or scientific evidence including causative factors, epidemiological studies or dose-response data may not exist for many toxic materials or harmful physical agents. Nevertheless, standards cannot be postponed because definitive medical or scientific evidence is not currently available. Indeed, standards need only be supported by the best available evidence. The legislative history makes it clear that "it is not intended that the Secretary be paralyzed by debate surrounding diverse medical opinion." House Committee on Education and Labor, Report No. 91–1291, 91st Cong., 2d sess., p. 18 (1970). This Congressional judgment is supported by the courts which have reviewed sandards promulgated under the Act. In sustaining the standard for occupational exposure to vinyl chloride (29 CFR 1910.1017), the U.S. Court of Appeals for the Second Circuit stated that "it remains the duty of the Secretary to act even in circumstances where existing methodology or research is deficient." *Society of the Plastics Industry Inc.* v. *Occupational Safety and Health Administration*, 509 F. 2d 1301 (C.A. 2 1975), cert den sub nom, *Firestone Plastic Co.* v. *United States Department of Labor*, 95 S.Ct. 1998, 4 L. Ed. 2d 482 (1975).

A similar rationale was applied by the U.S. Court of Appeals for the District of Columbia Circuit in reviewing the standard for occupational exposure to asbestos (29 CFR 1910.1001). The Court stated that:

> Some of the questions involved in the promulgation of these standards are on the frontiers of scientific knowledge, and consequently as to them insufficient data is presently available to make a fully informed factual determination. Decision-making must in that circumstance depend to a greater extent upon policy judgments and less upon purely factual judgments.

Industrial Union Department, AFL–CIO v. *Hodgson*, 499 F. 2d 467, 474 (C.A.-D.C. 1974).

In setting standards, the Secretary is expressly required to consider the feasibility of the proposed standards Senate Committee on Labor and Public Welfare, S. Rept. No. 91–1282, 91st Cong., 2d sess., p. 58 (1970). Nevertheless, considerations of technological feasibility are not limited to devices already developed and in use. Standards may require improvements in existing technologies or require the development of new technology. *Society of the Plastic Industry, Inc.* v. *Occupational Safety and Health Administration, supra* at 1309.

Where appropriate, the standards are required to include provisions for labels or other forms of warning to apprise employees of hazards, suitable protective equipment, control procedures, monitoring and measuring of employee exposure, employee access to the results of monitoring, and appropriate medical examinations. Moreover, where a standard prescribes medical examinations or other tests, they must be made available at no cost to the employees (section 6(b)(7)). Standards may also prescribe recordkeeping requirements where necessary or appropriate for enforcement of the Act or for developing information regarding occupational accidents and illnesses (section 8(c)).

III. EFFECTS OF EXPOSURE TO DBCP

The possible health effects of exposure to DBCP are illustrated by the results of acute and chronic toxicity studies in several animal species, and the recent discovery of sterility in a large number of male employees exposed to DBCP in the manufacture and formulation of pesticides. These effects may include, in addition to cancer and sterility, diminished renal function, and degeneration and cirrhosis of the liver.

A. STERILITY

Evidence in Animals

In 1961, Torkelson, *et al.* conducted experiments in which four animal species (male and female rats, guinea pigs, rabbits and monkeys) were exposed to DBCP by inhalation. The test animals were subjected to 50–66 exposures of 12 ppm DBCP over 70 to 92 days. A 40 to 50% mortality was observed in the rat study groups which, in most cases, was attributed to lung infections. Examination at autopsy showed damage to the lungs, kidneys, digestive system, and "severe atrophy and degeneration of the testes of all species." This effect was accompanied by a reduced sperm count, abnormal sperm cell development and degeneration of the seminiferous tubules. A 1970 subacute study by Faydysh *et al.* showed that a 70 mg/kg/day dose of DBCP, administered orally in oil solution for 45 days, produced a necrotic action on the testicles of white rats.

A more recent report in 1971 by Rakmatullaev disclosed that chronic (8 months) feeding exposures (5mg/kg/day) using DBCP produced a distinct decrease in sperm motility for male rats and a decrease in overall female fertility.

Further, a report on DBCP by Reznik and Sprinchan (1975) specifically identifies gonadotoxic effects in male and female rats. After a series of both acute (single dose, 100 mg/kg) and chronic (multiple dose, 10 mg/kg for 4–5 months) experiments it was concluded that DBCP not only severely affected spermatogenesis, but also had a profound effect on the estrous cycle of the female rats.

Evidence in humans

Concern for possible sterility effects resulting from exposure to DBCP first developed among employees of the Agricultural Chemical (Ag Chem) Division of Occidental Chemical Co. in Lathrop, Calif. For several years, the lack of children being born to families of men work-

ing in the Ag-Chem Plant was a topic of casual discussion among these employees. Within the last several months, there developed an increasing concern that the low birth rate among these families might be related to pesticide poisoning. Finally, at the suggestion of the employee union, the Oil, Chemical and Atomic Workers (OCAW), seven employees from the Ag Chem Plant volunteered for sperm counts to be taken.

Early in July 1977, laboratory reports of abnormal sperm counts taken from these seven men were sent to Dr. Donald Whorton, a physician at the University of California at Berkeley, who specializes in internal medicine and occupational diseases.

On the 22nd of July, Dr. Whorton performed sperm counts on five of the seven men. Again their sperm counts showed either oligospermia (low sperm count) or aspermia (no sperm). Arrangements were made with management for Dr. Whorton to see the remaining employees who worked in the Ag-Chem area or in the adjacent laboratory that did the quality control work. Twenty-six were production workers, 3 were supervisors, 4 were maintenance mechanics, 2 were clerical, and 6 were laboratory personnel. This made a total of 41 employees of which three were women.

The examination consisted of: (1) a complete medical history with emphasis on the reproductive tract as well as diseases and conditions that may cause sterility; (2) a work history; and (3) a thorough physical examination, including laboratory tests of a comprehensive nature.

The results of the physical exams were essentially normal, other than anticipated conditions based on medical history non-related to occupational exposure. The results of the blood analysis, kidney and renal functions, cholesterol, glucose, calcium and phosphorus determinations revealed no unexpected results.

As stated earlier, three of the 41 employees examined were women. Eleven of the 38 men had had previous vasectomies. The remaining 27 men had complete sperm analysis. A complete sperm analysis includes a sperm counts (sperms per cubic milliliter of seminal fluid), sperm motility (movement), and morphology (size and shape). Of these 27 men, 14 had sperm counts less than 40 million—considered abrnomally low by Dr. Whorton's criterion. Nine of the 14 were completely aspermic, having sperm counts of zero. Two had counts in the range of 1 million, one had a count in the range of 10 to 20 million, and two had counts in the range of 20 to 30 million. Dr. Whorton described sperm count as a relatively standard examination performed in most clinical laboratories and by a large number of urologists, primarily in evaluating male infertility.

Samples of sperm from all workers, except 4, examined by Dr. Whorton, were analyzed immediately upon collection, and the remaining ones were done within 12 hours or less. Sperm samples can be used up to 24 hours after the time they have been collected.

In all the men the testes were or normal size, and the serium testosterones of workers who had normal sperm counts were essentially normal. There was a marked difference in the FSH (follicle-stimulating hormone) levels and the LH (luteinizing hormone) levels in the eleven employees most severely affected (sperm count of 1 million or less) as compared to the 13 who had sperm counts of more than 40 million.

Ten of the 41 men were selected for open bilateral testicular biopsy on the basis of clinical findings and in order to learn all that could be learned of what was happening histologically to these testes. Also through a contract with NIOSH the rest of the employees in the Occidental plant are to be examined on a volunteer basis for sperm counts, FSH, LH, and serum testosterone. Examining a larger population may more clearly indicate the value of these tests in determining the adverse health effects.

Under a NIOSH contract, Dr. Whorton is engaged in a medical examination of some pesticide applicators and set-up men employed by Occidental Chemical to demonstrate the proper application and use of DBCP to farmers. At present, there is only limited data regarding these men, but already Dr. Whorton has observed abnormal sperm counts in approximately five out of nine workers.

Evidence of effects similar to those observed by Dr. Whorton have been reported to OSHA by the Dow Chemical Co. and Shell Chemical Co., the only two known U.S. producers of DBCP (both of these companies reported that they have recently suspended all operations involving manufacture and formulation of DBCP pesticides and have requested the return of all outstanding stocks).

In a letter dated September 1, 1977, the Medical Director of Dow Chemical Company reported that in their plant in Magnolia, Arkansas, DBCP production and formulation began in January 1976 and was discontinued in August 1977. To date 86 employees have been examined out of the total of approximately 150 who may have been exposed to DBCP. Among the 86 examined, aspermia has been found in 24 percent and 46 percent have oligospermia.

On September 28, 1977, telegrams were sent by the Assistant Secretary to Dow Chemical and Shell Chemical requesting any additional information on the health effects among employees exposed to DBCP.

In a reply telegram dated September 30, 1977, the Corporate Medical Director of Shell Chemical Co. reported additional data on employees exposed to DBCP who have abnormally low sperm counts. Seven of eleven employees from one plant had sperm counts of 40 million or less. Twenty-nine out of thirty-nine employees in a second plant had sperm counts less than 40 million. In the second plant, production of DBCP was discontinued in 1975. Shell estimates that employee exposures to DBCP have ranged from less than 100 ppb to 600 ppb for the past three years.

To date, no reply has been received from Dow.

In summary, sterility has been consistently found in employees in several plants whose exposure to DBCP was in some cases quite brief and in most cases at levels which have generally been regarded as low.

The possibility of other health effects cannot be dismissed as the examination of large numbers of exposed workers continues.

In 1961 Torkelson et al. two human volunteers exposed to concentrations of 1.7 ppm DBCP in chambers long enough to test the atmosphere for odors of the chemical. On the basis of this study he suggested precautions for safe handling to prevent ill effects from inhalation of DBCP. His summary and conclusions are as follows:

1,2-Dibromo-3-chloropropane was found to be but slightly irritating to the skin upon short single exposure. However, repeated applications caused necrosis of the dermis, the epidermis remaining fairly well preserved. The compound can be absorbed through the skin in toxic amounts. It is not likely to cause permanent injury to the eyes on single application but probably will be painful and cause transient irritation. The compound was found to be moderate to high in toxicity from single respiratory exposure and highly toxic on repeated exposure, producing damage even at 5 ppm, the lowest level studied. Excessive exposure to the vapors resulted in damage to the liver, kidneys, and various tissues including sperm cells and siminiferous tubules, dermis, bronchioles, renal collecting tubules, lens and cornea, and alimentary canal. Injury caused by this compound was noted to be particularly slow in healing. Precautions for safe handling of this compound are discussed.

B. CARCINOGENICITY

The National Cancer Institute undertook in 1972 studies of the possible carcinogenicity of DBCP, as one of a group of halogenated compounds. As early as 14 weeks after the initiation of administration by stomach tube of daily doses of 24 milligrams/kilogram (mg/kg) of DBCP dissolved in corn oil, 5 times per week, several female rats were found to have palpable mammary tumors. Female rats given daily doses of 12 mg/kg of DBCP had not developed mammary tumors. After the fourteenth week, the doses were increased to 30 and 15mg/kg/day. These doses were continued up to a total duration of the experiment of 52 weeks. During this period, 7 males and 11 females of the 50 rats of each sex given each dose of DBCP used in the experiment died without tumors. Seventeen of the male rats and 33 of the females given the high dose developed squamous carcinomas of the forestomach and 12 of the females had adenocarcinomas of the breast. Five female rats given the low dose of DBCP developed mammary carcinomas and 4 males and 14 females developed gastric carcinomas. One male among 20 rats of each sex used as vehicle controls developed a tumor that was not described more specifically. Groups of 50 male mice were given 160 or 80 mk/kg/day of DBCP for 14 weeks, 200 or 100 mg/kg/day for the next 13 weeks, and

260 or 130 mg/kg/day for 25 weeks. Numerically similar groups of female mice were given 120 or 60/mg/kg/day for the first 14 weeks and thereafter given the same doses as the males. Fourteen gastric carcinomas were observed in males and 9 in females on the high dose, and 3 in each sex on the low dose of DBCP. No mammary carcinomas developed in the female mice and no tumors of any sort developed in the vehicle controls (20 of each sex or each species).

A report in abstract form (Powers et al., 1975) at a later stage of the same study (after 78 weeks) changed the results in a quantitative way only, the incidence of mammary adenocarcinoma in female rats increasing to 54 percent and that of squamous cell carcinoma of the stomach exceeding 60 percent in the rats and 90 percent in the mice.

A draft of the final report of the contractor (Hazleton Laboratories America, 1977) to the National Cancer Institute reveals that male B6C3F1 mice received 160 or 80 mg/kg/day of DBCP by gavage for 11 weeks, 200 or 100 mg/kg/day for 14 weeks and 260 or 130 mg/kg/day for 22 or 33 weeks, respectively. The time weighted average daily doses were 219 mg/kg for the high-dose group and 113 mg/kg for the low-dose group. The female mice of the same strain received 120 or 60 mg/kg/day during the first 11 weeks and thereafter received the same doses as the males. The time-weighted average doses for the females were 209 mg/kg and 109 mg/kg. Osborne-Mendel rats of the two sexes were given identical doses: 24 or 12 mg/kg for the first 9 weeks, 15 mg/kg for 60 weeks (males) or 64 weeks (females) followed by a 5 week observation period for the males, for the low-dose group, and 30 mg/kg for 55 weeks for the high-dose group. For both male and female rats, the time-weighted average daily doses, 5 days/week, were 15 mg/kg for the low-dose group and 29 mg/kg for the high dose one.

The preliminary results are that the growth of male mice decreased slightly after the first 8 weeks on the high dose and after 22 weeks on the low dose. The growth of the females may have decreased after 32 weeks on the high dose. Mortality among the male mice increased after 36 weeks on the high dose and after 38 weeks on the low dose; that among the females increased after 36 weeks on the high dose and after 43 weeks on the low dose. The incidences of gastric cancer in male mice were 93.5 percent on the low dose and 97.9 percent on the high dose. No other tumors were reported in the mice but toxic nephropathy was found in 23.8 percent and 93.8 percent of male mice on the low and high doses, respectively.

The similar preliminary results for rats are that the growth of the females decreased slightly after 9 weeks on either the low or the high dose. Mortality among the male rats increased after 47 weeks on the high dose and after 60 weeks on the low dose; that among female rats increased after 28 weeks on the high dose and after 31 weeks on the low dose. The incidences of gastric cancer were 76 percent on the low dose and 59 percent on the high dose. In the females, adenocarcinoma of the breast appeared in 48 percent of the rats on the low dose and 62 percent of those on the high dose. In both sexes of this species, there were appreciable occurrences of other malignant and benign tumors (50 percent and 18 percent in males on the low and high doses, respectively, and 14 percent and 20 percent in the females on the low and high doses). The most common of these tumors were hemangiomas and hemangiosarcomas.

Among the control rats, mammary carcinoma occurred in 10 percent of the female colony controls and in none of the vehicle controls. Hemangiomas or hemangiosarcomas occurred in about 5.3 percent of male colony control rats and 15 percent of the females; they appeared in 5.0 percent of female vehicle control rats and in none of the male ones. Cancer of the forestomach was not found in control rats or mice.

Ward and Habermann (1974) reported that the squamous cell carcinomas of the forestomach induced in mice and rats by gavage of DBCP directly into the stomach invaded the wall of the stomach and metastasized to peritoneal surfaces, especially in rats. The metastatic tumors frequently were associated with peritonitis and abscesses.

An increased risk of cancer has not been seen with inhalation studies in rats; however, OSHA believes these results must be viewed as inconclusive due to the relatively brief duration of the studies.

There are indications from in vitro experiments that DBCP may cause mutagenic effects. Rosenkranz (1975) examined the effects of DBCP on two strains of *E. coli* and on two of the tester strains of *Salmonella typhimurium;* TA 1530 and TA 1538. DBCP was mutagenic for the first of these tester strains but not for the second, indicating that it induces mutations of the base substitution but not of the frame-shift type. While these results are not conclusive in themselves, they are not inconsistent with the animal carcinogenicity data. In general, a high correlation has been found between the results of in vitro mutagenicity tests and long term animal carcinogenicity studies.

For all practical purposes, the detection of carcinogenic activity of chemicals is based on animal experimentation. All chemical substances or mixtures that have been proven carcinogenic by direct observation in man have also been shown to be carcinogenic in experimental animals (with the possible exception of arsenic and benzene, still under experimental study). Because of the difficulties of epidemiological studies on humans exposed to potential carcinogens, there are usually no data which provide us with any evidence—one way or another—whether cancer is caused in man by a chemical that has been shown to be carcinogenic in animal studies. However, not to at least qualitatively assume that such a chemical does pose a carcinogenic threat to man seems imprudent and could lead to disaster.

In the preamble to the standards for the 14 carcinogens, OSHA stated:

> A major question of occupational carcinogensis relates to the extrapolation of results of animal experimentation to humans. The basis of numerous objections to the proposals is that, even assuming the validity of animal experiments, such do not furnish sufficient evidence that the substances involved are carcinogenic to humans. Extrapolation of results obtained by animal experimentation is alleged to be vitiated by several considerations: (a) that certain cancers are specific only to some species; (b) that the conditions of animal experiments are out of proportion to, and not consistent with conditions prevailing in industrial exposure; and (c) that no cancers have yet been detected in humans exposed to the substances. For those substances whose metabolism is understood, and is similar in both animals and man, the fact that they induce cancers in animals warrants the expectation that they will induce cancers in men. This applies to the substances which cause urinary bladder cancers in animals acting, not directly, but indirectly through the mediation of metabolites formed both in experimental animals and in exposed workers. This is also true of those substances which apparently require no metabolic alteration but attack a particular biologic system (e.g., respiratory tract, alimentary canal) which is similar in both animals and humans.
>
> The objections raise the much broader issue of human exposure to a chemical which is only known to have caused cancers in experimental animals. It is important to note that some opponents of the regulation of such chemicals do not advocate treating them as if they were harmless with respect to carcinogenic potential. Several employers, for instance insist that such substances must be treated with "care" or "respect," while also insisting that they call for significantly less protection than those substances known to be human carcinogens.
>
> We think it improper to afford less protection to workers when exposed to substances found to be carcinogenic only in experimental animals. Once the carcinogenicity of a substance has been demonstrated in animal experiments, the practical regulatory alternatives are to consider them either noncarcinogenic or carcinogenic to humans, until evidence to the contrary is produced. The first alternative would logically require, not relaxed controls on exposure, but exclusion from regulation. The other alternative logically leads to the treatment of a substance as if it was known to be carcinogenic to man.
>
> We agree with the Director of NIOSH, and the report of the Ad Hoc Committee on the Evaluation of Low Levels of Environmental Chemical Carcinogens to the Surgeon General, U.S. Public Health Service, April 22, 1970, that the second alternative is the responsible and correct one. This decision accords with the work practices of some who object to the proposed regulation. (39 FR 3756 at 3757–58.)

In view of the demonstration of carcinogenicity in two mammalian species, both sexes, at multiple dose levels, in well-designed studies, OSHA believes it is necessary, as a prudent policy matter, to treat DBCP as posing a potential carcinogenic risk to workers.

C. Other toxic effects. While sterility and a potential carcinogenic risk appear

to be the most important health effects associated with exposure to DBCP, animal studies and human experience have revealed a variety of other acute and chronic toxic effects of skin contact (percutaneous absorption), inhalation, and ingestion (Torkelson et al.; Rakhamatulaev, N. N.). Exposure to DBCP results in irritation of the eyes and respiratory passages. The central nervous system is depressed and may cause apathy, sluggishness, and ataxia.

The skin is slightly irritated upon short exposure. Repeated exposure causes necrosis of the dermis. Toxic amounts can be absorbed through the skin. Excessive exposure to the vapors results in damage to the liver, kidneys, and various tissues including dermic, bronchioles, renal collecting tubules, lens and cornea and alimentary canal. Injury caused by DBCP is particularly slow in healing.

These aspects of DBCP toxicity further indicate the necessity of limiting employee exposure by any route of entry.

IV. Summary and Explanation of the Proposal

In the development of this proposal, consideration has been given to all information and data available to OSHA at this time. OSHA has utilized reference works, studies, case histories, journal articles, testimony, recommendations by the staffs of NIOSH and OSHA, as well as widely accepted industrial hygiene practices.

The following section discusses some of the significant provisions of the proposed standard. The principal substantive changes in the proposal from the ETS are found in the following paragraphs:

(1) The permissible exposure limit—paragraph (c).
(2) Regulated areas—parargaph (e).
(3) Methods of compliance—paragraph (g).
(4) Respirators—paragraph (h).
(5) Emergencies—paragraph (i).
(6) Protective clothing and equipment—paragraph (j).
(7) Hygiene facilities and practices—paragraph (l).
(8) Medical surveillance—paragraph (m).
(9) Recordkeeping—paragraph (p).

Minor changes in language have been made in other provisions in recognition of "start-up" actions which would occur only under the ETS, and would not have to be repeated under a permanent standard.

1. Paragraph (a).—*Scope and application.* The proposed standard would apply to all employment where DBCP is present with the limited exception provided below. The principal activities that would be covered include the manufacture of DBCP, the formulation of pesticides containing DBCP, and related activities of packaging, repackaging, storage, transportation, and disposal of DBCP.

The proposed standard does not apply to exposures which result solely from the application and use of DBCP as a pesticide. In proposing this standard, OSHA is continuing a course of action, begun with the issuance of the ETS, to assure protection of workers exposed in manufacturing and formulation operations.

On September 8, 1977, concurrent with OSHA's issuance of the ETS, the Administrator of the Environmental Protection Agency announced his intention to take two suspension actions with respect to pesticide products containing DBCP, pursuant to his authority under Section 6(c) of the Federal Insecticide, Fungicide, and Rodenticide Act as amended (FIFRA), to suspend the registrations of a pesticide product whenever he determines that such action is necessary to prevent an "imminent hazard" during the time required for cancellation or change in classification proceedings.

The suspension notice (42 FR 48915) initiates two distinct suspension actions: A suspension of all pesticide products registered for food crop uses with respect to which residues of DBCP have been found or are anticipated on the edible portions of the food crops; and a conditional suspension with respect to all uses, based upon the Administrator's finding that an imminent hazard exists for pesticide applicators if DBCP products are used in accordance with current label restrictions.

The regulatory actions announced by EPA will have two important effects leading to increased protection of workers engaged in the application and use of DBCP as a pesticide. First, the suspension of use of DBCP pesticides for certain food crops will substantially reduce the number of applicator personnel and field workers who would otherwise have been exposed to DBCP under any circumstances.

Second, under the conditional suspension announced for all other uses, persons using DBCP for other uses will have to be certified applicators (and in some instances certified commercial applicators), or be working under the direct supervision of a certified applicator. Additionally, persons using DBCP for conditionally suspended uses will be required to wear protective clothing and respirators.

OSHA believes that this strategy of combined and cooperative regulatory actions by both EPA and OSHA is an effective approach to protecting all workers against the hazards of exposure to DBCP.

2. Paragraph (b).—*Definitions.* A definition has been added for "Emergency".

3. Paragraph (c).—*Permissible exposure limits.* The proposal would establish a permissible exposure limit of 1 part DBCP per billion parts of air (1 ppb) as an 8-hour time-weighted average. The ceiling permissible exposure limit for a 15 minute-maximum sample would be established as 10 ppb.

We cannot determine the exact mechanism of the toxic effects of DBCP, especially cancer, and cannot determine whether there is a safe level or threshold level below which reproductive effects and other effects would not occur.

Thus, while DBCP has not yet been conclusively demonstrated to be a carcinogen in humans, the evidence from several animal tests in mammalian species clearly indicates that, for the protection of the worker, we must regard DBCP as posing a potential carcinogenic risk. OSHA policy, which is based on the best available scientific evidence, and which is consistent with the policies and recommendations of nearly all public bodies which have addressed the problem of exposure to cancer-causing substances, has been and is that a substance which causes cancer in animals must be regulated as a human carcinogen. In the absence of a demonstrated "safe" or "no effect" level for human exposure to a carcinogen, it must be assumed, as a prudent policy matter, that no safe level exists. (See OSHA Cancer Policy Proposal, 42 FR 54148, October 4, 1977.)

Accordingly, the setting of an exposure level for DBCP cannot be based on a determination of a "safe" level which will eliminate the cancer and sterility hazard, but rather on a determination of a level which will minimize the hazard to the greatest extent possible, within the confines of feasibility.

In addition to limiting the 8-hour time weighted average exposure to 1 ppb, the proposal would require that no employee be exposed to DBCP in excess of 10 ppb averaged over any 15-minute period. An employee may be exposed to varying concentrations of DBCP during the course of the work day with some periods of exposure above 1 ppb and corresponding periods below 1 ppb. OSHA believes that the uncertainty regarding the concentrations and duration of exposure that may cause sterility or increase carcinogenic risk requires that the magnitude of brief excursions be limited. Consequently, a ceiling limit of 10 ppb averaged over any 15 minute period is proposed to be established.

An assessment of technological feasibility by an OSHA contractor (JRB Associates) indicates that an exposure limit of 1 ppb is technically possible for both DBCP manufacturing and formulation operations. The contractor did not find any present DBCP operations that meet this criteria, but did suggest the kinds of changes and processes that they believe necessary to attain such a limit. The contractor reports that one industrial operation does control exposures to 1 ppb (for bis-chloromethyl ether).

The contractor suggests that isolation of workers from the process equipment is necessary, and that this be accomplished by totally enclosing the equipment in a building or in a separate room within a building. Automatic or remote control of the different loading, process, and packaging operations would be necessary, since it is not contemplated that workers could enter the enclosure during the operation. In addition, the contractor believes that the enclosure would have to be maintained under negative

pressure with respect to the surroundings to prevent escape of process emissions. The effluent from the air-control system would have to be decontaminated to avoid exposures from unintended recirculation. Some work operations, such as tank car charging and discharging, would probably require the wearing of positive pressure atmosphere supplying respirators in addition to appropriate protective clothing.

OSHA recognizes that this projected technology is substantially different from the physical handling, blending and packaging processes which have characterized the DBCP operations, particularly formulation operations. OSHA requests further information as to the feasibility of reaching the permissible exposure limit solely through the use of engineering controls and supplementary work practices. In addition, information is sought as to any specific difficulties associated with the supplementary work practices and personal protective controls which might affect the feasibility of reducing exposure to the permissible exposure limit.

4. Paragraph (d).—*Notification of use.* The ETS required employers to notify the OSHA Area Director of the location of workplaces where DBCP is present, and to describe the conditions of use and exposures and the protective measures in effect. The proposal would not require the employers to report the same information again. However, any employer subsequently introducing DBCP into a workplace would be required to report.

5. Paragraph (e).—*Regulated areas.* The proposal would require the establishment of regulated areas where there is exposure to DBCP. OSHA believes that control of employee exposures, appropriate exposure monitoring, medical surveillance, and limitation of potential exposure to the smallest possible population all require regulated areas. The employer would be able to designate as "authorized" any person whose duties require his or her presence in the area.

6. Paragraph (f).—*Exposure monitoring.* The exposure monitoring provisions intend that the employer determine the exposure for each employee exposed to DBCP. This does not require separate measurements for each employee. If a number of employees perform essentially the same job under the same conditions, it may be sufficient to monitor a significant fraction of such employees and obtain results that are representative of the remaining employees.

Where exposures are determined to be above the permissible exposure limit, the employer would be required to monitor monthly. Otherwise the employer could monitor quarterly. "Exposure" in this connection means the airborne concentrations in the workers' breathing zone, without regard to the use of respirators.

The employer would also be required to monitor again if any changes in production, processes, control measures, or personnel make it likely that new or additional exposures to DBCP will result.

An assessment of available methodology for sampling and analysis of airborne concentrations of DBCP indicates that it is possible to monitor employee exposures of 1 part per billion and below. In particular, the samples may be collected by absorption of DBCP on charcoal contained in a suitable holder such as glass tubing through which a reasonable volume of air is drawn. Analysis is then performed by gas chromatography, probably using electron-capture detection. These techniques, although they require care, are readily available and should pose no insurmountable difficulties for the employers covered by this standard.

7. Paragraph (g).—*Methods of compliance.* This proposed standard would require the employer to institute engineering and work practice controls to reduce employee exposures to or below the permissible limits. In situations where engineering and work practice controls that can be instituted immediately will not reduce exposures to the permissible exposure limit, these controls must nonetheless be used to reduce exposures to the lowest feasible level and be supplemented by respirators. In addition, a compliance program to reduce exposures to within the permissible exposure limits solely by means of engineering and work practice controls must be developed and implemented. Written plans for this program must be developed and be furnished upon request for examination and copying to representatives of the Secretary, representatives of the Director or affected employees. These plans must be reviewed and updated periodically to reflect the current status of the program.

Engineering controls are the preferred means of compliance because they reduce exposure hazards in the workplace environment by removing the airborne contaminant. Engineering controls may include the installation of local exhaust ventilation, modification of a process so as to reduce emission of the contaminant into the workplace or substitution of another substance for DBCP. Work practices often are necessary for the effective operation of engineering controls, and they therefore are also preferred as a means of control.

Respirators are the least satisfactory means of control because of certain difficulties inherent in their use. Respirators are capable of providing good protection only if they are properly selected for the concentrations of airborne contaminants present, properly fitted to the employee, worn by the employee, and replaced when they have ceased to provide protection. While it is theoretically possible for all of these conditions to be met, it is more often the case that they are not. As a consequence, the protection of employees by respirators is not always effective.

8. Paragraph (h).—*Respirators.* The provisions of the proposal dealing with respirators differ from the ETS in three ways. First, the limits for the use of respirator types are adjusted to the proposed exposure limit of 1 ppb, with a ceiling of 10 ppb. Second, a specific limitation on the use of respirators would be established. This is consistent with the proposed hierarchy of controls provided under methods of compliance. Third, the use of air-purifying respirators would be prohibited. DBCP does not have any useful warning properties at concentrations where negative-pressure mode air-purifying respirators may be safely used. Consequently, there is no warning of respirator leakage or breakthrough. The odor threshold is estimated to be at least 300 times the possible limit for half-face chemical cartridge respirators, and 20 times the possible limit for gas masks. Because of the extremely serious consequences which have been found in human exposures at 100 to 600 ppb, we believe it imperative to prevent any risk of long-term undetected exposure. Consequently, the proposal would restrict the selection of respirators to atmosphere-supplying respirators. Malfunction of an atmosphere-supplying respirator is self-evident, and would cause the user to leave the work area to effect repairs.

The proposal would require that the employee be properly trained to wear the respirator, to know why the respirator is needed and to understand the limitations of the respirator. An understanding of the hazards involved is necessary to enable the employee to take steps for his or her own protection. The respiratory protection program implemented by the employer must conform with 29 CFR 1910.134. This section contains the basic requirements for use, cleaning, and maintenance of respirators.

To prevent skin irritation and to minimize the discomfort of respirator use, the proposal would require that employees must be allowed to periodically wash their faces and respirator facepieces in order to remove any accumulation of the DBCP or to reduce the chance of irritation from the wearing of the facepiece itself, such as a heat rash.

9. Paragraph (i).—*Emergencies.* The proposal would add a provision to assure employee evacuation and cleanup where spills occur or the concentration of DBCP may exceed the ceiling permissible exposure limit. Only employees with appropriate respirators and impermeable protective clothing would be allowed in the area until the situation were restored to normal.

10. Paragraph (j).—*Protective clothing and equipment.* The proposal would continue unchanged the requirement that the employer provide and assure that employees who are subject to skin or any eye contact use impermeable protective clothing or equipment in order to minimize these habards. OSHA is aware that since many formulating and producing facilities are located in warm climates, as a practical matter the impermeable protective clothing might require full body air conditioned suits.

The proposal would also require that the employer clean, launder, or dispose

of the required protective clothing to eliminate any potential exposure that might result were the clothing to be laundered by the employee at home, or in a commercial laundry.

The proposal would require that protective clothing be provided in a clean and dry condition daily. Since skin contact with DBCP creates a potenial for skin absorption, OSHA believes that the regular cleaning of contaminated work clothing plays an important role in the prevention of this hazard. The proposal would also require that protective clothing and equipment be maintained and replaced as needed in order to ensure effectiveness.

The proposal provides that the employer assure that all protective clothing is removed at the end of each work shift, and that the clothing that is to be laundered, cleaned, or disposed of be placed in a closable container. The purpose in requiring such a container is to prevent the contaminants on the clothing from being released into the ambient air or from being contacted by an individual handling the container.

Finally, the proposal would require employers to inform those who handle the contaminated protective clothing of the potentially harmful effects of exposure to DBCP. This provision is designed to make clear the need to use proper care in handling of the contaminated protective clothing.

11. Paragraph (k).—*Housekeeping.* Removal and prevention of accumulations of liquid deposits of DBCP or dusts containing DBCP, on all surfaces are important aspects in minimizing employee exposure. To assure that DBCP is not reintroduced into the workplace air, the standard would prohibit dry sweeping or the use of compressed air for cleaning floors and other surfaces where DBCP is found. The standard would also require that when DBCP is present in liquid form, or as a resultant vapor, that all containers or vessels be enclosed to the maximum extent feasible and tightly covered when not in use.

For disposal of waste scrap, equipment or debris containing DBCP, the standard would require that this material be collected and disposed of in sealed or closed containers which prevent the dispersion of DBCP outside the containers. State environmental protection agencies designate appropriate landfills for the disposal of such waste.

12. Paragraph (l).—*Hygiene facilities and practices.* The proposal would specify what hygiene facilities and practices are required for employee protection.

Change rooms would be required with separate storage for street and work clothing. OSHA believes that these facilities are necessary to minimize the duration of possible contacts with contaminated clothing, since DBCP is skin absorbable, and an irritant as well.

The proposal would require the provision of showers, and that employees be required to take showers at the end of the workshift to remove any DBCP from their bodies. Section 1910.141(d)(3), which would be implemented by the proposal, specifies requirements for adequate showers.

The proposal would also require that lavatory facilities be provided in accordance with § 1910.141(d) (1) and (2) to assure that sufficient facilities are available for employees to wash when leaving the regulated area to eat or use toilet facilities.

Provisions in the ETS prohibiting eating, smoking, drinking, or the keeping of food or smoking materials in regulated areas would be retained in the standard. Additionally, the proposal would prohibit the keeping of cosmetics in regulated areas to avoid the possibility that contamination would be inadvertently applied to the body.

The proposal requires employers to provide lunchrooms free of DBCP contamination readily accessible to employees working in a regulated area. The purpose of this requirement is to minimize the risk of employee exposure to DBCP by ingestion or inhalation during eating.

Employees would be able to eat, drink, smoke or apply cosmetics in lunchrooms, change rooms or other nonregulated areas.

13. Paragraph (m).—*Medical Surveillance.* The proposal would require that each employer institute a medical surveillance program for all employees who are, or will be, exposed to DBCP. OSHA believes that a medical surveillance program is necessary in dealing with the problem of employee exposure to DBCP.

The proposal would require a medical examination opportunity for each employee before the first assignment to work with DBCP and annually thereafter.

All examinations and procedures would be required to be performed by or under the supervision of a licensed physician and provided without cost to the employee. While the physician will usually be selected by the employer, the standard does not so mandate, leaving the employer free to institute alternative procedures such as joint selection with the employee or selection by the employee. Clearly, a licensed physician is the appropriate person to be conducting a medical examination. However, certain parts of the required examination (e.g. taking of a history) do not necessarily require a physician's expertise and may be conducted by another person under the supervision of the physician. As noted above, section 6(b)(7) of the Act mandates that medical examinations and procedures required by OSHA standards be provided at no cost to the employee.

The proposal provides that a work history, medical history and medical examination be performed. The content of the examination is consistent with identification of the adverse health effects that have been associated with exposure to DBCP and which OSHA therefore believes is appropriate for this proposal.

The required content of the medical examination in this proposal differs only slightly from the requirements of the ETS. In particular, the requirements for certain tests have been deleted based on consultation with Dr. Whorton and other physicians who indicated that based on their experience in examining the DBCP exposed workers, the deleted tests appear to have little or no relevance to diagnosing effects of exposure to DBCP. These tests include a complete urinalysis, a complete blood count, a thyroid profile, and the serum multiphasic analysis (SMA 12).

The standard would require that the employer provide the physician with certain information. This includes: (1) A copy of the regulation; (2) a description of the affected employee's duties as they relate to the employee's exposure; (3) the results of the employee's exposure monitoring; (4) if any personal protective equipment is used or is to be used; and (5) information from previous medical examinations of the affected employee to the extent that they are not readily available to the physician. The purpose of making this information available to the physician is to aid in evaluation of the employee's health in relation to his assigned duties and fitness to wear personal protective equipment when required.

The employer would be required to obtain a written opinion from the examining physician containing: (1) The results of the medical tests; (2) the physician's opinion as to whether the employee has any detected medical conditions which would place the employee at increased risk of material impairment of health from exposure to DBCP; (3) any recommended limitations upon the employee's exposure to DBCP and upon the use of protective clothing and equipment such as respirators; and (4) a statement that the employee has been informed by the physician in writing of the test results, and of any medical conditions which require further examination or treatment. This written opinion must not reveal specific findings or diagnoses unrelated to occupational exposure. A copy of the opinion must be provided to the affected employee by the employer.

The requirement that the employee be provided with a copy of the physician's written opinion will assure that the employee is informed of the results of the medical examination and may take any appropriate action. The purpose in requiring that specific findings or diagnoses unrelated to occupational exposure not be included in the written opinion is to encourage employees to submit to medical examinations by removing the fear that employers may find out information about their physical condition that has no relation to occupational exposures.

OSHA is seeking public input regarding the appropriateness of including a provision in the final DBCP standard which would protect employee participation in the medical surveillance program. This provision would extend economic protection to employees who participate in the medical surveillance program and

are removed or transferred from their job to protect them from material impairment of health. The purpose of this provision would be to encourage employees to participate in the medical surveillance program, which is an important part of OSHA's multifaceted prophylactic approach to occupational health.

The medical surveillance provision of the proposed standard contemplates that employers will limit the exposure of employees who are at increased risk of material impairment of health. Improved engineering controls, work practices, hygiene practices, respirators must be utilized to reduce employee exposures so that the employee is no longer at increased risk of material impairment of his or her health.

OSHA's primary goal is to assure that no employee suffers material impairment of health or functional capacity. The Agency does not favor transfer or removal as an alternative to controlling the level of a toxic substance in the workplace environment. Moreover, once full compliance with the permissible exposure limit is achieved by engineering controls and work practices, the need to transfer or remove employees from exposure to DBCP should arise infrequently.

However, it appears that limitation of exposure by transfer or removal of the employee from occupational exposure may, on occasion, be necessary to effectively protect employees from material impairment of health.

Therefore, OSHA is seeking public input as to whether the medical surveillance provisions of the DBCP standard should include a requirement for medical removal protection and the nature of such protection. This requirement could maintain the rate of pay, seniority and other rights of an employee for the time period, or a portion thereof, that the employee is transferred or removed from his or her job as a result of an increased health risk from exposure to DBCP.

A more complete discussion of the various issues and options available in this proceeding regarding medical removal protection may be found in the OSHA proposed standard on occupational exposure to lead published at 42 FR 46547 (September 16, 1977).

14. Paragraph (n).—*Employee information and training.* The proposal would require the employer to provide a training program for employees exposed to DBCP. OSHA believes that an information and training program is essential for the protection of employees, because an employee can do much to protect himself if informed of the nature of the hazards in the workplace. To be effective, an employee education system must, at the minimum, apprise the employee of the specific hazards associated with his work environment. For this reason, the employer would be required to inform each employee exposed to DBCP of the nature of the related health problems, the necessity for exposure control and the medical and industrial hygiene monitoring programs.

The content of the training program is intended to apprise the employees of: (1) The hazards to which they are exposed; (2) the necessary steps to protect themselves, including avoiding exposures, using respiratory protection and availing themselves of the opportunity for medical examinations; (3) their role in reducing exposures; and (4) the contents of the standard. Section 6(b)(7) of the Act makes it clear that these are appropriate goals of an employee training program, and the standard, therefore, includes them.

The employer would also be required to provide, upon request, all materials relating to the training program to the Secretary and the Director. This is intended to provide an objective check of compliance with the requirements of the standard.

15. Paragraph (o).—*Signs and labels.* OSHA believes that it is important, and section 6(b)(7) of the Act provides, that appropriate forms of warning, as necessary, be used to apprise employees of the hazards to which they are exposed in the course of their employment. OSHA believes, as a matter of policy, that employees should be given the opportunity to make informed decisions as whether to work at a job under the particular working conditions. Furthermore, OSHA believes that since control of safety and health problems involves the cooperation of employees, success of a program is highly dependent upon the employee's understanding of the hazards involved in the job.

In light of the serious nature of the hazard of exposure to DBCP, OSHA does not believe that periodic training alone will adequately apprise employees of the health hazards of DBCP. However, coupled with the training requirements, OSHA believes that the requirement to post signs and labels will adequately do so.

The standard would require that no statement which contradicts or detracts from the effect of any sign required by this paragraph shall appear on or near any such required sign.

Due to the hazardous nature of exposure to DBCP, OSHA believes that emphasis should be placed on warning employees and other persons about the danger of exposure. For this reason, the standard would include a requirement that caution labels be affixed to all containers containing DBCP and of the products containing it. The labeling provisions of the standard would also require the employer to assure that caution labels are affixed to any product containing the DBCP when such product leaves the employer's workplace. This requirement is designed to protect any other employees who will be handling, transporting, or using this product. The manufacturers and suppliers would be required to affix caution labels. The reason for this requirement is that the manufacturer or supplier is the employer creating the hazard and is in the best position to know whether the product does contain DBCP and therefore to warn other employers and their employees. However, where DBCP or products containing DBCP are sold, distributed or otherwise leave the employer's workplace bearing appropriate labels required by EPA under the regulations in 40 CFR Part 162, the labels required by this paragraph for products leaving the workplace need not be affixed.

16. Paragraph (p).—*Recordkeeping.* Section 8(c)(3) of the Act provides for the promulgation of regulations requiring employers to maintain accurate records of employee exposure to potentially toxic or harmful physical agents which are required to be monitored or measured.

The required retention time for medical surveillance records and exposure monitoring records would be extended to 40 years or the duration of exposure plus 20 years, whichever is longer. Carcinogenic induction, if it occurs in an exposed human population, has usually been found by medical surveillance 20 to 40 years after initial exposure. While present medical knowledge does not permit the establishment of exposure limits for carcinogens based on scientific information of the mechanism of carcinogenic induction, it is quite possible that such fundamental scientific knowledge will be developed within the next decade or two. At that point, knowledge of exposure levels of employees will be significant for both developing scientifically valid exposure limits, and for more precisely determining whether exposures may be safely continued for such employees.

The proposed standard provides that records must be kept to identify the employee and to accurately reflect the employee's exposure. Specifically, it must include: (a) The names, social security numbers and job classifications of the employees monitored, (b) the dates, number, duration and results of each of the samples taken, including a description of the representative sampling procedure used to determine employee exposure where applicable, (c) the type of respiratory protective devices worn by the employee, if any, and (d) a description of the sampling and analytical methods used, and evidence of their accuracy.

The proposal also requires that the employer keep an accurate medical record for each employee who is subject to medical surveillance. Section 8(c)(1) of the Act authorizes the promulgation of regulations requiring an employer to keep such records regarding the employer's activities relating to the Act as are necessary or appropriate for the enforcement of the Act or for developing information regarding the causes and prevention of occupational illnesses. OSHA believes that medical records (like exposure monitoring records) are both necessary and appropriate to both the enforcement of the standards and the development of information regarding the causes and prevention of illness.

As explained above, it is necessary to relate employees' medical conditions to their exposure in order to develop information regarding cause and prevention. Medical records are necessary and appropriate for this purpose. In addition,

medical records are necessary for the proper evaluation of an individual employee's health. For all of these reasons, medical records would be required.

The proposal requires that employees or their designated representatives be provided access to examine and copy records of required monitoring. The purpose of this provision is to assure current employees that their exposure is being properly monitored and recorded, and that they are working in a safe and healthful environment. Section 8(c)(3) of the Act explicitly provides "employees or their representatives with an opportunity to observe * * * monitoring or measuring * * * and to have access to the records thereof."

The proposal would require that employee medical records be made available upon request for examination and copying to the affected employee or former employee or to a physician designated by the affected employee or former employee. The purpose of this provision is to protect the employee's health by authorizing his designated physician to have access to medical records useful in the diagnosis of illness.

17. Paragraph (q).—*Observation of monitoring.* Section 8(c)(3) of the Act requires that employers provide employees or their representatives with the opportunity to observe monitoring of employee exposure to toxic substances or harmful physical agents. In accordance with this section, the proposal contains provisions for such observation of DBCP monitoring. To assure that the right to observe is meaningful, observers are entitled to receive an explanation of the measurement procedure, to observe all steps related to the measurement procedure, and record the results obtained.

The observer, whether an employee or designated representative, must be provided with, and is required to use, any personal protective devices required to be worn by employees working in the area that is being monitored, and must comply with all other applicable safety and health procedures.

18. Paragraph(s).—*Appendices.* The proposal includes three appendices: Appendix A titled "Substance Safety Data Sheet," Appendix B titled "Substance Technical Guidelines," and Appendix C titled "Medical Surveillance Guidelines." It should be noted that appendices are for informational purposes only. None of the statements contained therein should be construed as imposing a mandatory requirement not in the proposal, or negating any requirement which is imposed by the standard.

The information in Appendix A is specifically written for the employee. Appendix B contains additional scientific and technical information to aid the employer in complying with requirements of the standard. Appendix C gives the employer a means of providing the examining physician with an explanation of the potential health effects of exposure to DBCP and provides information needed by the physician to evaluate the results of the medical examination. Appendix C also lists other types of examinations, not required by the individual standard, which may help the physician in making an accurate determination of whether an employee should be exposed or should continue to be exposed to DBCP.

V. Environmental Impact

This section discusses the potential environmental impacts which the proposed standard for occupational exposure to DBCP may have on the workplace and external-to-workplace environments. This statement has been prepared in accordance with the provisions of the National Environmental Policy Act (42 U.S.C. 4321 et seq.) as well as the Guidelines of the Council on Environmental Quality (40 CFR Part 1500) and OSHA regulations (29 CFR Part 1999). Written comments and information on the projected impacts of this proposed standard for exposure to DBCP are solicited from all interested parties. In addition to this general request for comments, copies of this proposal and environmental impact statement will be sent to numerous Federal and State agencies, industry representatives, employee unions, and public interest groups with requests for their comments. The final date for receipt of written comments on environmental issues is December 28, 1977. All written comments on environmental issues should be addressed to: OSHA Office of Environmental and Economic Impact, Room N-3673, U.S. Department of Labor, 3rd and Constitution Avenues, N.W., Washington, D.C. 20210.

Testimony, data, arguments and related submissions on environmental issues associated with the proposed standard for DBCP will also be received at a public hearing on the proposal to be held on December 13, 1977, provided prehearing submission requirements, outlined in Section VII below, are complied with.

Additional copies of this proposed standard and draft environmental impact statement are available for review and copying in the OSHA Technical Data Center, Room S-6212, Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210.

Projected Environmental Impacts

The proposed standard for employee exposure to DBCP is expected to have a beneficial impact on the health of workers engaged in the manufacture, formulation and distribution of DBCP-containing pesticides. Incidences of aspermia, oligospermia and other adverse health effects, such as cancer and liver and kidney damage, may be reduced among these workers as a result of the proposal.

Because this proposed standard is designed to control worker exposures to DBCP in the manufacture and formulation of pesticides, minimal, if any, impact on the general human environment external to the workplace is anticipated with respect to air and water quality, solid waste disposal, land use or long-term productivity. Economic impacts due to proposed requirements for engineering, work practice and respiratory protective controls will occur in the DBCP pesticide manufacturing and formulating industries which will probably be passed on to the agricultural industry in the form of higher costs for DBCP-containing pesticides. Resultant increases in per acre crop production costs may be passed on as higher food costs to consumers.

The only major impacts which could occur as a result of the proposed standard would relate to land use and long-term productivity in the agricultural sector. Such impacts could occur if DBCP pesticide producers decide, as a result of the proposed standards, to discontinue DBCP production and the substance becomes unavailable to farmers. Declines in per acre crop yields would be expected for those crops for which no equally effective substitutes for DBCP exist, especially citrus, stone fruit crops and grapes. More acreage, requiring more land use, would have to be planted if overall production were to continue at the present rate in these sectors. Economic costs due to increased labor, land and planting costs would probably be reflected in consumer prices for these crops.

In addition to the above-mentioned crops, there are also no substitutes for DBCP nematocides for use in roses and other ornamental plants grown under glasshouse conditions. Loss of DBCP could have large impacts on this industry as well as impacts on consumer prices for floral products.

A. Air and Water Pollution Impact

The proposal specifies that occupational exposure to DBCP be reduced to a PEL of 1 part per billion (ppb) through the use of engineering controls, work practice controls and respiratory protective equipment. These controls are not anticipated to have an adverse impact on water or ambient air quality because the engineering equipment to be used for exposure reduction should result in a lower level of DBCP emission to the environment than in the past. (It is anticipated that closed systems, such as an exhaust ventilation coupled with air cleaning equipment will be used to control employee exposures.) The use of work practice controls may result in fewer releases of DBCP to the environment, but the use of respiratory protective equipment will have no impact on ambient air or water quality. Although there has been no indication that airborne DBCP or water pollution by DBCP have been public health problems, control of the pesticide's emissions in the workplace should result in cleaner air and water. At present, however, there is no evidence of a significant benefit to air and water quality, external to the workplace, as a result of this proposed standard.

B. Solid Waste Disposal

The proposal requires that DBCP waste, scrap, debris, bags, containers and equipment be disposed of in sealed bags or other closed containers which prevent dispersion of DBCP outside the containers. Disposal of DBCP waste may be accomplished within the plant by debromination or incineration of the chemical,

or by disposal in a secured land fill. However, as the OSHA proposal does not mandate a specific method of final waste disposal, the proposal should not result in any significant change in the methods currently used and, ultimately, should result in no significant environmental change in this area.

C. LAND USE IMPACT

If pesticide manufacturers and formulators are able to continue DBCP production while controlling employee exposures as mandated by the proposed standard, there should be no impact on land use. However, if DBCP operations are discontinued as a result of the proposed standard's economic costs, crops for which no equally effective substitute nematocides exist will be affected in the form of reduced yields. To counter this, and keep crop production at current levels, farmers will have to plant more acreage.

There is little data presently available concerning the amount of increased acreage which will be needed if DBCP becomes unavailable, and if no effective substitutes can be found. A California Department of Food and Agriculture subcommittee report noted that fruit tree loss without the pesticide could be as high as 60 percent. Dow Chemical Company has requested information on decreases in yield and additional acreage from its customers in a questionnaire distributed in March 1977. If any results from the Dow questionnaire become available they will be included in the final environmental impact statement to be issued prior to promulgation of the final occupational exposure standard for DBCP.

D. HUMAN RESOURCES IMPACT

The purpose of OSHA's proposed DBCP standard is to protect workers from the health hazards associated with exposures to DBCP in the manufacture and formulation of pesticides. DBCP exposure has been shown to cause oligospermia and aspermia in employees who handle the substance, and animal studies have strongly suggested the that compound can cause cancer in humans. In addition to these concerns, DCBP is known to cause other serious health effects in both humans and animals as detailed in section II. C of this notice.

Health benefits expected to result from the control and monitoring of employee exposure to DBCP include the prevention of future damage to employees' reproductive systems and resultant infertility, as well as reduction of the potential carcinogenic risk to employees. (There is, at present, no data on any benefits exposure control will have on those who have already suffered damage from occupational exposure.) Finally, the provisions of the proposal will probably cause a reduction in the incidence of the other toxic effects of DBCP exposure among employees.

A further impact of the proposed standard may be to increase the demand for medical services. This will not be of major significance for the major pesticide producers which already maintain medical surveillance programs. However, smaller facilities will probably have to acquire the services of additional medical personnel to comply with the provisions of the proposal. Due to the relatively small number of employees potentially involved, these additional medical requirements are not expected to have a significant environmental impact.

E. ENERGY IMPACT

The method of engineering control used to prevent employee exposure to DBCP above the proposed permissible exposure limit (PEL) will determine the amount of energy that will be needed as a result of the proposal. Presently, two methods are considered technologically feasible for the control of DBCP at the parts per billion level, according to a report prepared for OSHA by JRB Associates, Inc. The first is ventilation of workroom and process air with incineration of the exhaust stream to remove DBCP. For the two primary manufacturers of DBCP (Dow and Shell), this control method should result in annual increased energy consumption of approximately 604,000 gallons of fuel oil and 259,000 KWH of electricity. For the 80 formulators involved in the DBCP pesticide industry, annual increased energy needs are estimated to be 7,560,000 gallons of fuel oil and 2,419,000 KWH of electricity as a maximum based on an assumption that the present level of production would continue involving all 80 current registrants.

The other control method would involve ventilation of work-place and process air into activated charcoal filters. It appears that this method would be less energy intensive than the incineration method in that it would not involve any fuel oil costs, although additional electrical energy (330,000 KWH/yr/plant) will be needed to power the ventilation equipment.

Whichever of these control methods is chosen, the impacts of the increased energy consumption are not considered to be environmentally significant.

F. ECONOMIC IMPACT

OSHA has contracted with JRB Associates, Inc. to prepare an Economic Impact Assessment of the proposed standard for DBCP. Detailed costs of compliance with the proposal will be discussed in this document. See Section V of this notice for more detail.

ALTERNATIVES

There are two major areas of regulatory decision making which will affect the impact of the DBCP standard on the external environment. These are (1) permissible exposure limit (PEL) and (2) the methods by which compliance is mandated. The purpose of this section is to present the available alternatives and their probable environmental impacts.

A. PERMISSIBLE EXPOSURE LIMIT

Prior to the September 9, 1977, emergency temporary standard, there was no set exposure limit for DBCP. The decision to propose an eight-hour time-weighted average (TWA) exposure limit of 1 ppb, and a ceiling limit of 10 ppb averaged over any 15 minutes during the working day was based on data demonstrating the adverse health effects of exposure to DBCP. The proposed PEL for DBCP was chosen not as a "safe" or "no effect" level, but was based on OSHA's view that 1 ppb is the lowest feasible level achievable by engineering controls, as well as the lowest feasible detection level for industrial sampling and analysis. The level chosen for the final standard will depend on evidence submitted into the public record of this rulemaking proceeding.

Alternatives available to OSHA in setting a PEL for DBCP are discussed below. The magnitude of environmental impact resulting from the institution of any of these alternatives is dependent upon whether they result in a decrease in the availability of DBCP-containing pesticides.

Alternative One: Establish a PEL Between 1 and 10 ppb

The alternative of establishing a PEL at some level between 1 and 10 ppb may be preferable for pesticide manufacturers and formulators in that control to such levels may require the installation of less costly engineering controls. This alternative is not recommended for health reasons, however, as DBCP is a sterilant and a suspected carcinogen for which no safe exposure level has been demonstrated.

Alternative Two: Establish a PEL Between 0.0 and 1 ppb

Although a PEL at a level less than 1 ppb may be more desirable than the proposed PEL based on health considerations, environmental sampling and monitoring systems for detecting such low levels may be economically and technically infeasible for industrial uses.

Alternative Three: Zero Employee Exposure

If OSHA's final regulation for DBCP states that employers may not allow employees any detectable exposure to DBCP, production and formulation of DBCP pesticides would probably be either discontinued or greatly decreased. This would affect not only the pesticide industry, but the agricultural industry and consumer prices as well.

B. METHODS OF COMPLIANCE

The proposed standard requires that compliance be achieved through the use of engineering controls, work practice controls and personal protective equipment. Personal protective equipment is to be used, however, only when engineering and work practice controls are insufficient to reduce employee exposures to within the PEL.

Engineering controls may include enclosed processing, remote control operations, and exhaust ventilation coupled with air scrubbing equipment. These controls should not have significant bene-

ficial or adverse impacts upon the general human environment external to the workplace, although their use could have great impacts on the future health and fertility of DBCP production employees.

Work practice controls and personal protective equipment should have little if any impact on the environment. However, the difference in cost between engineering and these other types of controls may be the deciding factor as to whether financially marginal plants continue DBCP operations. As shown in the preceding section, the impact of an occupational standard for DBCP on the environment is contingent on the production of the compound. If OSHA's regulation is deemed to be too costly to attain, thereby eliminating domestic production of DBCP (and assuming no importation of DBCP-containing pesticides), there may be significant reductions in domestic crop production.

Alternatives involved in the methods of compliance section are primarily concerned with establishing a particular priority among the types of controls (engineering, work practice, and respiratory protective equipment). While sole reliance on the use of engineering and work practice controls is now proposed, an alternative would be to allow the employer complete freedom in choosing the method of control without any required priority systems.

C. OTHER ALTERNATIVES

Alternatives to the establishment of an occupational health standard for DBCP would include discontinuing use of DBCP-containing pesticides and instituting other pest control methods such as biological and cultural controls, sanitation practices (especially for glasshouse and nursery growers), the use of other existing nematocides and the development of new ones.

Alternative One: Biological and Cultural Controls

Biological and cultural techniques such as following, flooding crop rotation and the use of resistant or immune varieties have been used before the development of DBCP and the other chemical nematocides, however, they have been shown to be costly and relatively ineffective under field conditions.

Alternative Two: Sanitation Practices

By breaking the disease triangle (pathogen, susceptible host, favorable environment) it is theoretically possible to eliminate the presence of a virulent pathogen in nursery stock. However, to achieve a commercially clean (pest-free) nursery stock, a complicated procedure of planting and analysis of the stock plants is necessary to assure the elimination of parasitic nematodes. To date, DBCP is the best post-planting prophylactic nematocide for perennials.

Alternative Three: Alternative Chemicals

There are several existing chemical alternatives to DBCP, such as 1,3-dichloropropene (Telone II, DD), ethylene dibromide, SMDC (Vapam), MIT (Vorlex) and methyl bromide. These are required in much greater quantities than DBCP and their costs are also significantly higher. Developing new chemical compounds as DBCP substitutes has several implications. Under the present state of research and federal and state regulations, two to three years of testing will be required to determine their effectiveness and residues on a wide variety of crops. New or modified application techniques and machinery may be needed to accurately deliver small volumes of granular and liquid formulations. Finally, additional problems resulting from the use of present and future nematocides include high mammalian toxicity, safe handling and delivery, possible development of resistance and associated economic costs.

It should be noted that the development of these other alternatives, while possible, is not under the jurisdiction of OSHA. Under the Occupational Safety and Health Act of 1970, OSHA can only concern itself with regulating employee exposure.

In compliance with the Federal Food, Drug and Cosmetic Act (Sec. 402, 702), the Food and Drug Administration (FDA) is monitoring DBCP-food residues in eight of its 22 districts located in California, the South and southeastern portions of the United States. FDA will furnish the information it gathers on DBCP residues to EPA, for use in EPA's suspension and cancellation proceedings. In addition, FDA may ask EPA to recommend "action levels" for DBCP residues in certain commodities. Action levels are set by FDA in the exercise of its prosecutional discretion under Section 307 of the Food, Drug and Cosmetic Act. An action level represents a level of illegal residue above which the FDA generally will take enforcement action.

RELATIONSHIP WITH OTHER FEDERAL ACTIONS

On September 8, 1977, the Environmental Protection Agency (EPA) initiated two suspension actions against DBCP under Section 6(c) of the Federal Insecticide, Fungicide and Rodenticide Act, as amended (FIFRA).[1] The first suspension action sought to prohibit the sale and distribution of DBCP for use on 19 food crops on which EPA anticipated that residues of DBCP were likely to occur, and the use of DBCP on these crops.[2] The second suspension action sought to mitigate the hazard to DBCP applicators, by conditionally prohibiting the sale, distribution and use of all DBCP products. Pesticide manufacturers could get relief from the prohibition, however, by agreeing on an interim basis to restrict the use of the product to certified applicators (and in some cases certified professional applicators), and by requiring the use of protective clothing and respirators. Pursuant to the statutory procedure, EPA extended an opportunity to manufacturers of DBCP products to request an expedited administrative hearing on whether the statutory standard for suspension was met or exceeded. Three manufacturers filed requests for hearings, which were later withdrawn. Since no hearing requests remain outstanding, it is anticipated that EPA very soon will proceed to implement the two suspension actions it set in motion on September 8, 1977, by issuing suspension orders.

Suspension is a form of interim relief under FIFRA; it is a way of prohibiting the sale, distribution and use of a pesticide product during the course of the more time-consuming cancellation procedures which are required under FIFRA to ban a pesticide permanently.

In order to implement a suspension by issuing a suspension order, the statute requires EPA to have already issued, or to issue at the same time as the suspension order, a notice of intent to cancel the registrations of the pesticide. [See FIFRA Section 6(c).] In order to facilitate a rapid decision on DBCP cancellation, EPA issued a Rebuttable Presumption Against Registration (RPAR) against all DBCP pesticides on the same day that it announced its intention to suspend and conditionally suspend DBCP pesticide. [42 FR 48026 (September 22, 1977).][3]

VI. ECONOMIC IMPACT

In accordance with Executive Order 11821 (39 CFR 41501, November 29, 1974), Executive Order 11949 (42 FR 1017, January 5, 1977), OMB Circular No. A-107 (January 28, 1975), and Secretary's Order No. 15-75 (40 FR 54484, November 24, 1975), and administrative instructions thereto (U.S. Department of Labor Temporary Directive No. 1, November 17, 1975), OSHA has assessed the potential economic impact of this proposal. Based on the economic identification criteria specified in section 5(c) of Secretary's Order No. 15-75, OSHA has

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[1] See EPA's "Notice of Intent to Suspend and Conditionally Suspend Registrations of Pesticide Products Containing Dibromochloropropane," 42 FR 48915 (September 26, 1977).

[2] Broccoli, brussels sprouts, cabbage, carrots, cauliflower, celery, cucumbers, eggplant, endive, lettuce, melons, parsnips, peanuts, peppers, radishes, squash, strawberries, tomatoes and turnips.

[3] The RPAR process is set out in 40 CFR Section 162.11 of EPA's regulations. In broad summary, these regulations provide that a Rebuttable Presumption Against Registration (RPAR) shall arise if the Agency determines that a pesticide meets or exceeds any of the risk criteria set forth in 40 CFR Section 162.11(a)(3). If it is determined that such a presumption has arisen, registrants, pesticide users and interested persons are afforded an opportunity to submit evidence in rebuttal of the presumption. Those persons may also submit evidence as to whether the economic, social, and environmental benefits of the use of the pesticide outweigh the risks of use. If the risk presumptions are not rebutted, the benefits evidence submitted will be considered by the Agency in determining whether the risks of the uses of the pesticide exceed the benefits of the uses, and, if so, what regulatory action should be taken.

concluded that the subject matter of this proposal is not a "major" action which would necessitate further economic impact evaluation or the preparation of an Economic Impact Statement, and so certifies pursuant to section 4(a) of the Secretary's Order.

JRB Associates, Inc. has prepared for OSHA an economic assessment entitled, "Economic Impact Assessment of the Occupational Safety and Health Administration's Standard on Occupational Exposure to 1,2 Dibromo-3-chloropropane (DBCP)".

The study includes assessment of the technological feasibility of compliance as well as an estimate of compliance costs. The effects on other variables, such as employment, prices, productivity, market structure, exports, and imports; and the consumption of energy and critical materials, are also considered.

Notice is being given of the availability of this assessment to afford interested parties the earliest possible opportunity to contribute comments, information and data. Evaluation of the economic and technological feasibility of the final standard will be based on the entire record of the rulemaking proceeding, including all oral and written comments made part of the record, as well as the economic assessment.

The economic assessment of the proposed DBCP standard is now available for public inspection and copying at the following address: Technical Data Center, Occupational Safety and Health Administration, U.S. Department of Labor, Room S-6212, Third and Constitution Avenue, N.W., Washington, D.C. 20210. (Telephone: 202–523–7894)

VII. References

The studies and other data listed below, as well as the additional material referred to in this document, represent the principal sources upon which the proposal is based. A complete set of the references is available for examination and copying at the OSHA Technical Data Center, Docket Office, Room S6212, U.S. Department of Labor, 2nd Street and Constitution Avenue NW., Washington, D.C., between 8:30 a.m. and 4:30 p.m. Monday through Friday, legal holidays excepted.

1. Faydysh, E. V., N. N. Rakhmatullaev and V. A. Varshavskii: The cytotoxic action of Nemagon in a subacute experiment. *Med. Zh. Uzbekistana*, 1:64–5, 1970 (Russian).

2. Olsen, W. A., R. T. Habermann, E. K. Weisburger, J. M. Ward and J. H. Weisburger: Induction of stomach cancer in rats and mice by halogenated aliphatic fumigants. *Journal of the National Cancer Institute*, 51(6):1993–1995, 1973.

3. Powers, M. B., R. W. Voelker, N. P. Page, E. K. Weisburger and H. F. Kraybill: Carcinogenicity of Ethylene Dibromide (EDB) and 1,2-Dibromo-3-chloropropane (DBCP) after oral administration in rats and mice.

4. Rakhmatullaev, N. N.: Hygienic characteristics of the nematocide Nemagon in relation to water pollution control. *Hyg. Sanit.*, 36(3):344–348, 1971 (Russian).

5. Reznik, Ya. B., and G. K. Sprinchan: Experimental data on the gonadotoxic effect of Nemagon. *Gig. Sanit.*, 6:101–102, 1975 (Russian).

6. Rosencranz, H. S.: Genetic activity of 1, 2-Dibromo-3-choloropropane, a widely used fumigant. *Bulletin of Environmental Contamination and Toxicology*, 14:1, 1975.

7. Torkelson, T. R, S. E. Sadek, V. K. Rowe, J. K. Kodama, H. H. Anderson, G. S. Loquvam, and C. H. Hine: Toxicologic investigations of 1.2-Dibromo-3-choloropropane. *Toxicology and Applied Pharmacology*, 3:545–559, 1961.

8. Ward, J., and R. T. Habermann: Pathology of stomach cancer in rats and mice induced with the agricultural chemicals Ethylene dibromide and Dibromochloropropane. *The Bulletin of the Society of Pharmacological and Environmental Pathologists*. Vol. II, No. 2, June 1974.

9. Weisburger, E. K.: Carcinogenicity studies on halogenated hydrocarbons. *Environmental Health Perspectives*, In press.

10. Whorton, Donald, M.D. OSHA interview with Dr. Whorton on August 31, 1977 concerning the sterility of workers exposed to 1,2-Dibromo-3-chloropropane at Occidental Chemical Company's Lathrop, Calif. plant.

11. Telegram, Dr. Eula Bingham, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, Washington, D.C. to Dr. V. K. Rowe, Dow Chemical USA, 1803 Building, Midland, Mich. requesting information on employee exposure to 1,2-Dibromo-3-chloropropane and Ethylene dibromide; dated August 30, 1977.

12. Letter from Dow Chemical USA, Dr. Benjamin B. Holder responding for Dr. Rowe to Dr. Eula Bingham, Assistant Secretary for Occupational Safety and Health, U.S. Department of Labor, dated September 1, 1977.

13. Telegram, Dr. Eula Bingham, Assistant Secretary of Labor for Occupational Safety and Health, Occupational Safety and Health Administration, U.S. Department of Labor, Washington, D.C. to Dr. R. E. Joyner, Corporate Medical Director, Shell Oil Co. P.O. Box 2463, Houston, Tex. 77001 requesting information on employee exposure to 1,2-Dibromo-3-chloropropane and Ethylene dibromide; dated August 30, 1977.

14. Telegram from Shell Oil Co., Dr. R. E. Joyner MD, Corporate Medical Director to Dr. Eula Bingham, Assistant Secretary for Occupational Safety and Health, U.S. Department of Labor, dated August 31, 1977.

15. Telegram, U.S. Department of Labor, Occupational Safety and Health Administration, Office of Field Coordination, to all producers and users of 1,2-Dibromo-3-chloropropane, dated August 12, 1977.

16. Letter, Occupational Health Guideline for 1,2-Dibromo-3-chloropropane (DBCP), U.S. Department of Labor, Occupational Safety and Health Administration, sent to all producers and users of DBCP, dated August 25, 1977.

17. Joint NIOSH-OSHA Standards Completion Program, Respirator Decision Logic, August 2, 1976. Occupational Safety and Health Administration, Washington, D.C. 20210.

18. Proposal for 29 CFR Part 1990 published October 4, 1977, 42 FR 541488. Identification classification, and regulation of certain toxic substances. Identification, classification, and regulation of toxic substances posing a potential occupational carcinogenic risk. Occupational Safety and Health Administration, Directorate of Health Standards, Washington, D.C. 20210 (January 1977).

19. California Department of Food and Agriculture, Subcommittee — Alternative Methods and Chemicals to Use for DBCP, September 8, 1977.

20. Economic Impact Assessment of the Occupational Safety and Health Administration's Standard on Occupational Exposure to 1,2-Dibromo-3-Chloropropane (DBCP)," prepared by JRB Associates, Inc., October, 1977.

21. Telegram, Dr. R. E. Joyner, Corporate Medical Medical Director, Shell Oil Co., Houston, Tex., to Dr. Eula Bingham, Assistant Secretary of Labor, U.S. Department of Labor, Washington, D.C., transmitting revised counts of employees with below-normal sperm counts. September 30, 1977.

VIII. Public Participation—Notice of Hearing

NOTE.—The following instructions for public participation in the rulemaking proceeding on the proposed permanent standard for DBCP are different in several respects and supersede those of the ETS, especially as to the dates for required submissions of notices of appearances, witness statements, etc.

Interested persons are invited to submit written data, views and arguments with respect to the ETS and this proposal. These comments must be received on or before December 2, 1977, and submitted in quadruplicate to the Docket Officer, Docket No. H–061, Room S6212, U.S. Department of Labor, 3rd Street and Constitution Avenue, NW., Washington, D.C. 20210. Written submissions must clearly identify the provisions of the ETS or this proposal which are addressed and the position taken with respect to each issue.

The data, views and arguments that are submitted will be available for public inspection and copying at the above address. All timely written submissions will be made a part of the record of this proceeding.

Pursuant to section 6(b)(3) of the Act, an opportunity to submit oral testimony concerning the issues raised by the ETS and the proposed standard, including the economic and environmental impacts, will be provided at an informal public hearing scheduled to begin at 9:30 a.m. on December 13, 1977, in the Department of Labor Auditorium, New Department of Labor Building, 3rd Street and Constitution Avenue, NW., Washington, D.C. 20210.

Notices of Intention to Appear, Filing of Testimony and Evidence

All persons desiring to participate at the hearing, must file in quadruplicate a notice of intention to appear, received on or before December 2, 1977, addressed to Mr. Kevin Conlon, OSHA Division of Consumer Affairs, Docket No. H–061, Room N–3635, U.S. Department of Labor, 3rd Street and Constitution Avenue NW., Washington, D.C. 20210, telephone: 202–523–8024.

The notices of intention to appear, which will be available for inspection and copying at the OSHA Technical Data Center—Docket Office (Room S6212), telephone 202–523–7895, must contain the following information:

(1) The name, address, and telephone number of each person to appear;

(2) The capacity in which the person will appear;

(3) The approximate amount of time requested for the presentation;

(4) The specific issues that will be addressed;

(5) A statement of the position that will be taken with respect to each issue addressed; and

(6) In addition, for any party requesting more than 15 minutes for a presentation at the hearing, or who will submit documentary evidence, must provide in quadruplicate the complete text of the testimony including any documentary evidence to be presented at the hearing. This material must also be received by December 2, 1977, and will be available for inspection and copying at the Technical Data Center—Docket Office. Each submission will be reviewed in light of the amount of time requested in the notice of intention to appear. In those instances where the information contained in the submission does not justify the amount of time requested, a more appropriate amount of time will be allocated and the participant will be notified of that fact.

Any party who has not substantially complied with the requirement to provide the complete test of testimony and documentary evidence may be limited to a 15 minute presentation, and to provide the complete text of testimony and documentary evidence may be requested to return for questioning at a later time.

CONDUCT OF HEARINGS

The hearing will commence at 9:30 a.m. on December 13, 1977, with resolution of any procedural matters relating to the proceeding. The hearing will be conducted in accordance with 29 CFR Part 1911. The hearing will be conducted in as expedited a manner as possible consistent with a full development of the record and the rights of the parties.

The hearing will be presided over by an Administrative Law Judge who will have all the powers necessary or appropriate to conduct a full and fair informal hearing as provided in 29 CFR Part 1911. Following the close of the hearing or of any posthearing comment period, the presiding Administrative Law Judge will certify the record to the Assistant Secretary of Labor for Occupational Safety and Health. The proposal will be reviewed in light of all oral and written submissions received as part of the record, and a standard will be issued based on the entire record in this proceeding.

AUTHORITY

This document was prepared under the direction of Eula Bingham, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, Third Street and Constitution Avenue NW., Washington, D.C. 20210.

Accordingly, pursuant to sections 6(b), 6(c), 8(c) and 8(g) of the Occupational Safety and Health Act of 1970 (84 Stat. 1593, 1596, 1599, 1600; 29 U.S.C. 655, 657), the Secretary of Labor's Order No. 8–76 (41 FR 25059), and 29 CFR Part 1911, it is hereby proposed to amend Part 1910 of Title 29, Code of Federal Regulations by revising § 1910.1044 as set forth below. In addition, appropriate amendments would be made to Parts 1915–1918 and 1926 to clarify the applicability of this § 1910.1044 to the maritime and construction industries.

NOTE.—It is hereby certified that the economic and inflationary impact of this proposed regulation has been evaluated in accordance with Executive Orders 11821 and 11949.

Signed at Washington, D.C., this 26th day of October 1977.

EULA BINGHAM,
Assistant Secretary of Labor.

Part 1910 of Title 29 of the Code of Federal Regulations is proposed to be amended by revising § 1910.1044 to read as follows:

§ 1910.1044 1,2 - dibromo-3-chloropropane.

(a) *Scope and application.* This section applies to the production, reaction, release, packaging, repackaging, storage, transportation, handling, or use of 1,2-dibromo-3-chloropropane (DBCP), Chemical Abstracts Service Registry No. 96–12–8, except that this section does not apply to exposure to DBCP which results solely from the application and use of DBCP as a pesticide.

(b) *Definitions.* "Authorized person" means any person specifically authorized by the employer and whose duties require the person to be present in regulated areas; and any person entering such areas as a designated representative of employees exercising an opportunity to observe employee exposure monitoring.

"DBCP" means 1,2-dibromo-3-chloropropane.

"Director" means the Director, National Institute for Occupational Safety and Health, U.S. Department of Health, Education, and Welfare, or designee.

"Emergency" means any occurrence such as, but not limited to equipment failure, rupture of containers, or failure of control equipment which does, or is likely to, result in any massive release of DBCP.

"OSHA Area Office" means the Area Office of the Occupational Safety and Health Administration having jurisdiction over the geographic area where the affected workplace is located.

"Assistant Secretary" means the Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, or designee.

(c) *Permissible exposure limits.* (1) *Inhalation.* (i) *Time-weighted average limit (TWA).* The employer shall assure that no employee is exposed to an airborne concentration in excess of 1 part DBCP per billion parts of air (ppb) as an 8-hour time-weighted average.

(ii) *Ceiling limit.* The employer shall assure that no employee is exposed to an airborne concentration in excess of 10 parts DBCP per billion parts of air (ppb) as averaged over any 15 minutes during the working day.

(2) *Dermal and eye exposure.* The employer shall assure that no employee is exposed to eye or skin contact with DBCP.

(d) *Notification of use.* Within ten (10) days following the introduction of DBCP into the workplace, every employer who has a workplace where DBCP is present shall report the following information to the nearest OSHA Area Office for each such workplace:

(1) The address and location of each workplace in which DBCP is present;

(2) A brief description of each process or operation which may result in employee exposure to DBCP;

(3) The number of employees engaged in each process or operation who may be exposed to DBCP and an estimate of the frequency and degree of exposure that occurs;

(4) A brief description of the employer's safety and health program as it relates to limitation of employee exposure to DBCP.

(e) *Regulated areas.* (1) The employer shall establish regulated areas where there is any exposure to DBCP.

(2) The employer shall limit access to regulated areas to authorized persons.

(f) *Exposure monitoring.* (1) *General.* Determinations of airborne exposure levels shall be made from air samples that are representative of each employee's exposure to DBCP over an 8-hour period. (For the purposes of this paragraph, employee exposure is that exposure which would occur if the employee were not using a respirator.)

(2) *Initial.* Each employer who has a place of employment in which DBCP is present shall monitor each workplace and work operation to accurately determine the airborne concentrations of DBCP to which employees may be exposed.

(3) *Frequency.* (i) If the monitoring required by this section reveals employee exposures to be below the permissible exposure limit, the employer shall repeat these determinations at least quarterly.

(ii) If the monitoring required by this section reveals employee exposure to be in excess of any of the permissible exposure limit, the employer shall repeat these determinations for each such employee at least monthly. The employer shall continue these monthly determinations until at least two consecutive measurements, taken at least seven (7) days apart, are below the permissible exposure limit. Thereafter the employer shall monitor at least quarterly.

(4) *Additional.* Whenever there has been a production, process, control or personnel change which may result in any new or additional exposure to DBCP, or whenever the employer has any other reason to suspect a change which may result in new or additional exposures to DBCP, additional monitoring which complies with this paragraph (f) shall be conducted.

(5) *Employee notification.* (i) Within five (5) working days after the receipt of monitoring results, the employer shall notify each employee in writing of results which represent the employee's exposure.

(ii) Whenever the results indicate that employee exposure exceeds the permissible exposure limit the employer shall include in the written notice a statement that the permissible exposure limit was exceeded and a description of the correc-

tive action being taken to reduce exposure to or below the permissible exposure limit.

(6) *Accuracy of measurement.* The method of measurement shall be accurate, to a confidence level of 95 percent, to within plus or minus 25 percent for concentrations of DBCP at or above the permissible exposure limit.

(g) *Methods of compliance.* The employer shall control employee exposures to airborne concentrations of DBCP to within the permissible exposure limit, and shall protect against employee exposure to eye or skin contact with DBCP by engineering controls, work practices, and personal protective equipment as follows:

(1) *Priority of compliance methods.* (i) *Engineering and work practice controls.* The employer shall institute engineering or work practice controls to reduce and maintain employee exposures to DBCP to within the permissible exposure limit, except to the extent that the employer establishes that such controls are not feasible.

(ii) *Respiratory protection.* Whenever the engineering and work practice controls which can be instituted are not sufficient to reduce employee exposures to within the permissible exposure limit, the employer shall nonetheless use them to reduce exposures to the lowest level achievable by these controls and shall supplement them by use of respiratory protection which complies with the requirements of paragraph (h) of this section.

(2) *Compliance program.* (i) The employer shall establish and implement a written program to reduce employee exposures to DBCP to or below the permissible exposure limit lowest feasible level solely by means of engineering and work practice controls as required by paragraph (g) (1) of this section.

(ii) Written plans for these compliance programs shall include at least the following:

(*a*) A description of each operation or process resulting in employee exposure to DBCP;

(*b*) Engineering plans and other studies used to determine the controls for each process;

(*c*) A report of the technology considered in meeting the permissible exposure limit;

(*d*) A detailed schedule for the implementation of engineering or work practice controls; and

(*e*) Other relevant information.

(iii) Written programs required under this paragraph (g) (2) shall be submitted upon request to the Assistant Secretary and the Director, and shall be available at the worksite for examination and copying by the Assistant Secretary, the Director, and any affected employee or designated representative of employees.

(h) *Respirators.* (1) *General.* Where respiratory protection is required under this section, the employer shall select, provide and assure the use of respirators. Respirators shall be used in the following circumstances:

(i) During the period necessary to install or implement feasible engineering and work practice controls; or

(ii) In work operations such as maintenance and repair activities in which engineering and work practice controls are not feasible; or

(iii) In work situations where feasible engineering and work practice controls are not yet sufficient to reduce exposure within the permissible exposure limit; or

(iv) In emergencies.

(2) *Respirator selection.* (i) Where respirators are required under this section, the employer shall select and provide, at no cost to the employee, the appropriate respirator from Table 1 below and shall assure that the employee wears the respirator provided.

(ii) The employer shall select respirators from among those approved by the National Institute for Occupational Safety and Health (NIOSH) under the provisions of 30 CFR Part 11.

TABLE 1.—*Respiratory protection for DBCP*

Concentration not greater than:	*Respiratory protection*
10 p/b	(1) Any supplied-air respirator. (2) Any self-contained breathing apparatus.
50 p/b	(1) Any supplied-air respirator with full facepiece, helmet, or hood. (2) Any self-contained breathing apparatus with full facepiece.
1,000 p/b	(1) A Type C supplied-air respirator operated in pressure-demand or other positive pressure or continuous flow mode.
2,000 p/b	(1) A Type C supplied-air respirator with full facepiece operated in pressure-demand or other positive pressure mode, or with full facepiece, helmet, or hood operated in continuous flow mode.
Greater than 2,000 p/b or entry and escape from unknown concentrations.	(1) A combination respirator which includes a Type C supplied-air respirator with full facepiece operated in pressure-demand or other positive pressure or continuous flow mode and an auxiliary self-contained breathing apparatus operated in pressure-demand or positive pressure mode. (2) A self-contained breathing apparatus with full facepiece operated in pressure-demand or other positive pressure mode.
Fire-fighting	(1) A self-contained breathing apparatus with full facepiece operated in pressure-demand or other positive pressure mode.

(3) *Respirator program.* (i) The employer shall institute a respiratory protection program in accordance with 29 CFR 1910.134 (b, (d), (e), and (f).

(ii) Employees who wear respirators shall be allowed to wash their faces and respirator facepieces to prevent potential skin irritation associated with respirator use.

(i) *Emergency situations.* (1) *Written plans.* (i) A written plan for emergency situations shall be developed for each workplace in which DBCP is present and in which there is a possibility of an emergency. Appropriate portions of the plan shall be implemented in the event of an emergency.

(ii) The plan shall specifically provide that employees engaged in correcting emergency conditions be equipped as required in paragraphs (h) and (j) of this section until the emergency is abated.

(iii) Employees not engaged in correcting the emergency shall be removed and restricted from the area and normal operations in the affected area shall not be resumed until the emergency is abated.

(2) *Alerting employees.* Where there is a possibility of employee exposure to DBCP in excess of the ceiling limit due to the occurrence of an emergency, a general alarm shall be installed and maintained to promptly alert employees of such occurrences.

(j) *Protective clothing and equipment.* (1) *Provision and use.* Where eye or skin contact with liquid or solid DBCP may occur, employers shall provide at no cost to the employee, and assure that employees wear impermeable protective clothing and equipment in accordance with § 1910.132 and § 1910.133 to protect the area of the body which may come in contact with DBCP.

(2) *Removal and storage.* (i) The employer shall assure that employees remove DBCP contaminated work clothing only in change rooms provided in accordance with (l) (1) of this section.

(ii) The employer shall assure that no employee takes DBCP contaminated protective devices and work clothing out of the change room, except those employees authorized to do so for the purpose of laundering, maintenance, or disposal.

(iii) DBCP-contaminated protective devices and work clothing shall be placed and stored in closed containers which prevent dispersion of the DBCP outside the container.

(iv) Containers of DBCP contaminated protective devices or work clothing which are to be taken out of change rooms or the workplace for laundering or disposal, or for any other reason, shall bear labels in accordance with paragraph (o) (3) of this section.

(3) *Cleaning and replacement.* (i) The employer shall clean, launder, repair, or replace protective clothing and equipment required by this paragraph to maintain their effectiveness. In addition, the employer shall provide clean protective clothing and equipment at least daily to each affected employee.

(ii) The employer shall inform any person who launders or cleans DBCP-contaminated protective clothing or equipment of the potentially harmful effects of exposure to DBCP.

(iii) The employer shall prohibit the removal of DBCP from protective clothing and equipment by blowing or shaking.

(k) *Housekeeping.* (1) *Surfaces.* (i) All surfaces shall be maintained free of accumulations of DBCP.

(ii) Dry sweeping and the use of air for the cleaning of floors and other surfaces where DBCP dust or liquids are found is prohibited.

(iii) Where vacuuming methods are selected, either portable units or a permanent system may be used.

(*a*) If a portable unit is selected, the exhaust shall be attached to the general workplace exhaust ventilation system or collected within the vacuum unit, equipped with high efficiency filters or other appropriate means of contaminant removal, so that DBCP is not reintroduced into the workplace air; and

(*b*) Portable vacuum units used to collect DBCP may not be used for other cleaning purposes and shall be labeled as prescribed by paragraph (o)(3) of this section.

(iv) Cleaning of floors and other contaminated surfaces may not be performed by washing down with a hose, unless a fine spray has first been laid down.

(2) *Liquids.* Where DBCP is present in a liquid form, or as a resultant vapor, all containers or vessels containing DBCP shall be enclosed to the maximum extent feasible and tightly covered when not in use.

(3) *Waste disposal.* DBCP waste, scrap, debris, bags, containers, or equipment shall be disposed of in sealed bags or other closed containers which prevent dispersion of DBCP outside the container.

(l) *Hygiene facilities and practices.* (1) *Change rooms.* The employer shall provide clean change rooms equipped with storage facilities for street clothes and separate storage facilities for protective clothing and equipment whenever employees are required to wear protective clothing and equipment in accordance with paragraph (j) of this section.

(2) *Showers.* (i) The employer shall assure that employees working in the regulated area shower at the end of the work shift.

(ii) The employer shall provide shower facilities in accordance with 29 CFR 1910.141(d)(3).

(3) *Lunchrooms.* The employer shall provide lunchroom facilities which have a temperature controlled, positive pressure, filtered air supply, and which are readily accessible to employees working in regulated areas.

(4) *Lavatories.* (i) The employer shall assure that employees working in the regulated area wash their hands and face prior to eating.

(ii) The employer shall provide a sufficient number of lavatory facilities which comply with 29 CFR 1910.141(d)(1) and (2).

(5) *Prohibition of activities in regulated areas.* The employer shall assure that, in regulated areas, food or beverages are not present or consumed, smoking products and implements are not present or used, and cosmetics are not present or applied. (These items may be kept, and these activities may be conducted in lunchrooms, change rooms and showers required under paragraphs (l)(1)–(4) of this section.)

(m) *Medical surveillance.* (1) *General.* The employer shall institute a program of medical surveillance for each employee who is or will be exposed, without regard to the use of respirators, to DBCP. The employer shall provide each such employee with an opportunity for medical examinations and tests in accordance with this paragraph. All medical examinations and procedures shall be performed by or under the supervision of a licensed physician, and shall be provided without cost to the employee.

(2) *Frequency and content.* At the time of initial assignment, and annually thereafter, the employer shall provide a medical examination including at least the following:

(i) A medical and occupational history with emphasis on reproductive history.

(ii) A physical examination with emphasis on the genitourinary tract, testicle size (males), and body habitus including a determination of sperm count of non-vasectomized males.

(iii) A serum specimen shall be obtained and the following determinations made by radioimmunoassay techniques utilizing NIH specific antigen or one of equivalent sensitivity:

(*a*) Serum follicle stimulating hormone (FSH);

(*b*) Serum luteinizing hormone (LH); and

(*c*) Serum testosterone (males) or serum total estorgen (females).

(iv) Any other tests deemed appropriate by the examining physician.

(3) *Additional examinations.* If the employee for any reason develops signs or symptoms commonly associated with exposure to DBCP, the employer shall provide appropriate examination and emergency medical treatment.

(4) *Information provided to the physician.* The employer shall provide the following information to the examining physician:

(i) A copy of this regulation and its appendices;

(ii) A description of the affected employee's duties as they relate to the employee's exposure;

(iii) The level of DBCP to which the employee is exposed; and

(iv) A description of any personal protective equipment used or to be used.

(5) *Physician's written opinion.* (i) The employer shall obtain a written opinion from the examining physician which shall include:

(*a*) The results of the medical tests performed;

(*b*) The physician's opinion as to whether the employee has any detected medical condition which would place the employee at an increased risk of material impairment of health from exposure to DBCP;

(*c*) Any recommended limitations upon the employee's exposure to DBCP or upon the use of protective clothing and equipment such as respirators; and

(*d*) A statement that the employee was informed by the physician of the results of the medical examination, and any medical conditions which require further examination or treatment.

(ii) The employer shall instruct the physician not to reveal in the written opinion specific findings or diagnoses unrelated to occupational exposure to DBCP.

(iii) The employer shall provide a copy of the written opinion to the affected employee.

(n) *Employee information and training.* (1) *Training program.* (i) The employer shall institute a training program for all employees who may be exposed to DBCP and shall assure their participation in such training program.

(ii) The employer shall assure that each employee is informed of the following:

(*a*) The information contained in Appendices A, B, and C;

(*b*) The quantity, location, manner of use, release, or storage of DBCP and the specific nature of operations which could result in exposure to DBCP as well as any necessary protective steps;

(*c*) The purpose, proper use, and limitations of respirators;

(*d*) The purpose and description of the medical surveillance program required by paragraph (m) of this section; and

(*e*) A review of this standard.

(2) *Access to training materials.* (i) The employer shall make a copy of this standard and its appendices readily available to all affected employees.

(ii) The employer shall provide, upon request, all materials relating to the employee information and training program to the Assistant Secretary and the Director.

(o) *Signs and labels.*—(1) *General.* (i) The employer may use labels or signs required by other statutes, regulations, or ordinances in addition to or in combination with, signs and labels required by this paragraph.

(ii) The employer shall assure that no statement appears on or near any sign or label required by this paragraph which contradicts or detracts from the required sign or label.

(2) *Signs.* (i) The employer shall post signs to clearly indicate all work areas where DBCP may be present. These signs shall bear the legend:

DANGER

1,2-Dibromo-3-chloropropane
(*Insert appropriate trade or common names*)

CANCER HAZARD
AUTHORIZED PERSONNEL ONLY

(ii) Where airborne concentrations of DBCP exceed the permissible exposure limit, the signs shall bear the additional legend:

RESPIRATOR REQUIRED

(3) *Labels.* (i) The employer shall assure that precautionary labels are affixed to all containers of DBCP and of products containing DBCP, and that the labels remain affixed when the DBCP or products containing DBCP are sold, distributed, or otherwise leave the employer's workplace. Where DBCP or products containing DBCP are sold, distributed or otherwise leave the employer's workplace bearing appropriate labels required by EPA under the regulations in 40 CFR Part 162, the labels required by this paragraph need not be affixed.

(ii) The employer shall assure that the precautionary labels required by this paragraph are readily visible and legible. The labels shall bear the following legend:

DANGER

1,2-Dibromo-3-chloropropane

CANCER HAZARD

(p) *Recordkeeping.*—(1) *Exposure monitoring.* (i) The employer shall establish and maintain an accurate record of all monitoring required by paragraph (f) of this section.

(ii) This record shall include:

(*a*) The dates, number, duration and results of each of the samples taken, including a description of the sampling procedure used to determine representative employee exposure;

(*b*) A description of the sampling and analytical methods used;

(*c*) Type of respiratory protective devices worn, if any; and

(*d*) Name, social security number, and job classification of the employee monitored and of all other employees whose exposure the measurement is intended to represent.

(iii) The employer shall maintain this record for at least 40 years or the duration of employment plus 20 years, whichever is longer.

(2) *Medical surveillance.* (i) The employer shall establish and maintain an accurate record for each employee subject to medical surveillance required by paragraph (m) of this section.

(ii) This record shall include:

(*a*) A copy of the physician's written opinion.

(*b*) Any employee medical complaints related to exposure to DBCP;

(*c*) A copy of the information provided the physician as required by paragraph (m)(3) of this section; and

(*d*) A copy of the employee's work history.

(iii) The employer shall maintain this record for at least 40 years or the duration of employment plus 20 years, whichever is longer.

(3) *Availability.* (i) The employer shall assure that all records required to be maintained by this section be made available upon request to the Assistant Secretary and the Director for examination and copying.

(ii) The employer shall assure that employee exposure monitoring records required by this section be made available, upon request, for examination and copying to the affected employee or former employee, and their designated representatives.

(iii) The employer shall assure that employee medical records required to be maintained by this section be made available, upon request, for examination and copying to the affected employee or former employee, or to a physician designated by the affected employee or former employee or designated representative.

(q) *Observation of monitoring.*—(1) *Employee observation.* The employer shall provide affected employees, or their designated representatives, an opportunity to observe any monitoring of employee exposure to DBCP conducted under paragraph (f) of this section.

(2) *Observation procedures.* (i) Whenever observation of the measuring or monitoring of employee exposure to DBCP requires entry into an area where the use of protective clothing or equipment is required, the employer shall provide the observer with personal protective clothing or equipment required to be worn by employees working in the area, assure the use of such clothing and equipment, and require the observer to comply with all other applicable safety and health procedures.

(ii) Without interfering with the monitoring or measurement, observers shall be entitled to:

(a) Receive an explanation of the measurement procedures;

(b) Observe all steps related to the measurement of airborne concentrations of DBCP performed at the place of exposure; and

(c) Record the results obtained.

(r) *Effective date.* This section shall become effective thirty days following publication in the FEDERAL REGISTER.

(s) *Appendices.* The information contained in the appendices is not intended, by itself, to create any additional obligations not otherwise imposed or to detract from any existing obligation.

APPENDIX A—SUBSTANCE SAFETY DATA SHEET FOR DBCP

I. SUBSTANCE IDENTIFICATION

A. Synonyms and trades names: DBCP; Dibromochloropropane; Fumazone (Dow Chemical Company TM); Nemafume; Nemagon (Shell Chemical Co. TM); Nemaset; BBC 12; and OS 1879.

B. DBCP can be found as a: concentrate; liquid; solution; and granules;

C. DBCP is used on crops including: cotton; soybeans; fruits; nuts; vegetables; and ornamentals.

D. DBCP can be applied to crops: before planting; during planting; and after planting.

II. HEALTH HAZARD DATA

E. Permissible exposure: Exposure may not exceed either:

1. 1 part DBCP per billion parts of air (1 ppb) averaged over the eight-hour work day; or

2. 10 parts DBCP per billion parts of air (10 ppb) averaged over any 15 minute period in the workday.

II. HEALTH HAZARD DATA

A. Routes of entry: Employees may be exposed:

1. Through inhalation (breathing);
2. Through ingestion (swallowing);
3. Skin contact; and
4. Eye contact.

B. Effects of overexposure:

1. Acute exposure: DBCP may cause drowsiness, irritation of the eyes, nose, throat and skin, nausea and vomiting. In addition, overexposure may cause damage to the lungs, liver or kidneys.

2. Chronic exposure: Prolonged or repeated exposure to DBCP may cause injury to the lungs, liver or kidneys. DBCP has been associated with sterility in humans and laboratory animals. It also has been shown to produce cancer in laboratory animals and has been determined to constitute an increased risk of cancer in man.

3. Reporting Signs and Symptoms: If you develop any of the above signs or symptoms that you think are caused by exposure to DBCP, you should inform your employer.

III. EMERGENCY FIRST AID PROCEDURES

A. Eye exposure: If DBCP liquid or dust containing DBCP gets into your eyes, wash your eyes immediately with large amounts of water, lifting the lower and upper lids occasionally. Get medical attention immediately. Contact lenses should not be worn when working with DBCP.

B. Skin exposure: If DBCP liquids or dusts containing DBCP get on your skin, immediately wash using soap or mild detergent and water. If DBCP liquids or dusts containing DBCP penetrate through your clothing, remove the clothing immediately and wash. If irritation is present after washing get medical attention.

C. Breathing: If you or any person breathe in large amounts of DBCP, move the exposed person to fresh air at once. If breathing has stopped, perform artificial respiration. Do not use mouth-to-mouth. Keep the affected person warm and at rest. Get medical attention as soon as possible.

D. Swallowing: When DBCP has been swallowed and the person is conscious, give the person large amounts of water immediately. After the water has been swallowed, try to get the person to vomit by having him touch the back of his throat with his finger. Do not make an unconscious person vomit. Get medical attention immediately.

E. Rescue: Notify someone. Put into effect the established emergency rescue procedures. Know the locations of the emergency rescue equipment before the need arises.

IV. RESPIRATORS AND PROTECTIVE CLOTHING

A. Respirators: You may be required to wear a respirator for non-routine activities or in emergencies and while your employer is in the process of reducing DBCP exposures through engineering controls. If respirators are worn, they must have a National Institute for Occupational Safety and Health (NIOSH) approval label (Older respirators may have a Bureau of Mines Approval label). For effective protection, a respirator must fit your face and head snugly. The respirator should not be loosened or removed in work situations where its use is required. DBCP does not have a detectable odor except at 1,000 times or more above the permissible exposure limit. If you can smell DBCP while wearing a respirator, the respirator is not working correctly; go immediately to fresh air. If you experience difficulty breathing while wearing a respirator, tell your employer.

B. Protective Clothing: You must wear for your protection impermeable work clothing provided by your employer. (Standard rubber and neoprene protective clothing do not offer adequate protection).

DBCP must never be allowed to remain on the skin. Clothing and shoes should not be

allowed to become contaminated with the material, and if they do, they should be promptly removed and not worn again until completely free of the material. Turn in impermeable clothing that has developed leaks for repear or replacement.

C. Eye protection: You must wear splash-proof safety goggles where there is any possibility of DBCP liquid or dust contacting your eyes.

V. PRECAUTIONS FOR SAFE USE, HANDLING, AND STORAGE

A. DBCP must be stored in tightly closed containers in a cool, well-ventilated area.

B. If your work clothing may have become contaminated with DBCP, or liquids or dusts containing DBCP, you must change into uncontaminated clothing before leaving the work premises.

C. You must promptly remove any non-impermeable clothing that becomes contaminated with DBCP. This clothing must not be reworn until the DBCP is removed from the clothing.

D. If your skin becomes contaminated with DBCP, you must promptly and thoroughly wash or shower with soap or mild detergent and water to remove any DBCP from your skin.

E. You must not keep food, beverages, cosmetics, or smoking materials, nor eat or smoke, in areas where DBCP is handled, processed or stored.

F. If you handle DBCP, you must wash your hands thoroughly with soap or mild detergent and water, before eating, smoking or using toilet facilities.

G. Ask your supervisor where DBCP is used in your work area and for any additional safety and health rules.

VI. ACCESS TO INFORMATION

A. Each year, your employer is required to inform you of the information contained in this Substance Safety Data Sheet for DBCP. In addition, your employer must instruct you in the safe use of DBCP, emergency procedures, and the correct use of protective equipment.

B. Your employer is required to determine whether you are being exposed to DBCP. You or your representative have the right to observe employee exposure measurements and to record the result obtained. Your employer is required to inform you of your exposure. If your employer determines that you are being overexposed, he is required to inform you of the actions which are being taken to reduce your exposure.

C. Your employer is required to keep records of your exposure and medical examinations. Your employer is required to keep exposure and medical data for at least 40 years or the duration of your employment plus 20 years, whichever is longer.

D. Your employer is required to release exposure and medical records to your physician upon your written request.

APPENDIX B—SUBSTANCE TECHNICAL GUIDELINES FOR DBCP

I. PHYSICAL AND CHEMICAL DATA

A. Substance Identification: 1. Synonyms: 1,2-dibromo-3-chloropropane; DBCP, Fumazone; Nemafume; Nemagon; Nemaset; BBC 12; OS 1879. DBCP is also included in agricultural pesticides and fumigants which include the phrase "Nema * * *" in their name.

2. Formula: $C_3H_5Br_2Cl$.

3. Molecular Weight: 236.

B. Physical Data: 1. Boiling point (760 mm HG): 195C (383F).

2. Specific gravity (water=1): 2.093.

3. Vapor density (air=1 at boiling point of DBCP): Data not available.

4. Melting point: 6C (43F).

5. Vapor pressure at 20C (68F): 0.8 mm Hg.

6. Solubility in water: 1000 ppm.

7. Evaporation rate (Butyl Acetate=1): very much less than 1.

8. Appearance and odor: Dense yellow or amber liquid with a pungent odor at high concentrations. Any detectable odor of DBCP indicates overexposure.

II. FIRE EXPLOSION AND REACTIVITY HAZARD DATA

A. Fire: 1. Flash point: 170F TOC.

2. Autoignition temperature: Data not available.

3. Flammable limits in air, percent by volume: Data not available.

4. Extinguishing media: Carbon dioxide, dry chemical.

5. Special fire-fighting procedures: Do not use a solid stream of water since a stream will scatter and spread the fire. Use water spray to cool containers exposed to a fire.

6. Unusual fire and explosion hazards: None known.

7. For purposes of complying with the requirements of 1910-106, liquid DBCP is classified as a class III A combustible liquid.

8. For the purpose of complying with § 1910.309, the classification of hazardous locations as described in article 500 of the National Electrical Code for DBCP shall be Class I Group D.

9. For the purpose of compliance with § 1910.157, DBCP is classified as a Class B fire hazard.

10. For the purpose of compliance with § 1910.178, locations classified as hazardous locations due to the presence of DBCP shall be Class I, Group D.

11. Sources of ignition such as smoking or open flames are prohibited where DBCP presents a fire or explosion hazard.

B. Reactivity: 1. Conditions contributing to instability: None known.

2. Incompatibilities: Reacts with chemically active metals, such as aluminum, magnesium and tin alloys.

3. Hazardous decomposition products: Toxic gases and vapors (such as HBr, HCl and carbon monoxide) may be released in a fire involving DBCP.

4. Special precautions: DBCP will attack some rubber materials and coatings.

III. SPILL, LEAK AND DISPOSAL PROCEDURES

A. If DBCP is spilled or leaked, the following steps should be taken:

1. The area should be evacuated at once and re-entered only after thorough ventilation.

2. Ventilate area of spill or leak.

3. If in liquid form, collect for reclamation or absorb in paper, vermiculate, dry sand, earth or similar material.

4. If in solid form, collect spilled material in the most convenient and safe manner for reclamation or for disposal.

B. Persons not wearing protective equipment must be restricted from areas of spills or leaks until cleanup has been completed.

C. Waste Disposal Methods: 1. For small quantities of liquid DBCP, absorb on paper towels, remove to a safe place (such as a fume hood) and burn the paper. Large quantities can be reclaimed or collected and atomized in a suitable combustion chamber equipped with an appropriate effluent gas cleaning device. If liquid DBCP is absorbed in vermiculite, dry sand, earth or similar material and placed in sealed containers it may be disposed of in a state-approved sanitary landfill.

2. If in solid form, for small quantities, place on paper towels, remove to a safe place (such as a fume hood) and burn. Large quantities may be reclaimed. However, if this is not practical, dissolve in a flammable solvent (such as alcohol) and atomize in a suitable combustion chamber equipped with an appropriate effluent gas cleaning device. DBCP in solid form may also be disposed in a State-approved sanitary landfill.

IV. MONITORING AND MEASUREMENT PROCEDURES

A. Exposure above the permissible exposure limit.

1. *Eight-hour exposure evaluation.* Measurements taken for the purpose of determining employee exposure under this section are best taken so that the average eight-hour exposure may be determined from a single 8-hour sample or two (2) four-hour samples. Air samples should be taken in the employee's breathing zone (air that would most nearly represent that inhaled by the employee).

2. *Ceiling evaluation.* Measurements taken for the purpose of determining employee exposure under this section must be taken during periods of maximum expected airborne concentrations of DBCP in the employee's breathing zone. A minimum of three measurements should be taken in one work shift. The highest of all measurements taken is an estimate of the employee's exposure.

3. *Monitoring techniques.* The sampling and analysis under this section may be performed by collecting the DBCP vapor on charcoal adsorption tubes with subsequent chemical analyses. The method of measurement chosen should determine the concentration of airborne DBCP to an accuracy of plus or minus 25 percent. If charcoal tubes are used, a total volume of 10 liters should be collected at a flow rate of 50 cc. per minute for each tube. Analyze the resultant samples as you would samples of halogenated solvent.

B. Since many of the duties relating to employee protection are dependent on the results of monitoring and measuring procedures, employers should assure that the evaluation of employee exposures is performed by a competent industrial hygienist or other technically qualified person.

V. PROTECTIVE CLOTHING

Employees should be required to wear appropriate protective clothing to prevent any possibility of skin contact with DBCP. Because DBCP is absorbed through the skin, it is important to prevent skin contact with both liquid and solid forms of DBCP. Protective clothing should include impermeable coveralls or similar fullbody work clothing, gloves, headcoverings, and workshoes or shoe coverings. Standard rubber and neoprene gloves do not offer adequate protection and should not be relied upon to keep DBCP off the skin. DBCP should never be allowed to remain on the skin. Clothing and shoes should not be allowed to become contaminated with the material, and if they do, they should be promptly removed and not worn again until completely free of the material. Any protective clothing which has developed leaks or is otherwise found to be defective should be repaired or replaced. Employees should also be required to wear splash-proof safety goggles where there is any possibility of DBCP contacting the eyes.

VI. HOUSEKEEPING AND HYGIENE FACILITIES

1. The workplace must be kept clean, orderly, and in a sanitary condition;

2. Dry sweeping and the use of compressed air is unsafe for the cleaning of floors and other surfaces where DBCP dust or liquids are found. To minimize the contamination of air with dust, vacuuming with either portable or permanent systems must be used. If a portable unit is selected, the exhaust must be attached to the general workplace exhaust ventilation system, or collected within the vacuum unit equipped with high efficiency

filters or other appropriate means of contamination removal and not used for other purposes. Units used to collect DBCP must be labeled as prescribed in § 1910.1044(o) (DBCP standard).

3. Adequate washing facilities with hot and cold water must be provided, and maintained in a sanitary condition. Suitable cleansing agents should also be provided to assure the effective removal of DBCP from the skin.

4. Change or dressing rooms with individual clothes storage facilities must be provided to prevent the contamination of street clothes with DBCP. Because of the hazardous nature of DBCP, contaminated protective clothing must be stored in closed containers for cleaning or disposal.

VII. MISCELLANEOUS PRECAUTIONS

A. Store DBCP in tightly closed containers in a cool, well ventilated area.

B. Use of supplied-air suits or other impervious clothing (such as acid suits) may be necessary to prevent skin contact with DBCP. Supplied-air suits should be selected, used, and maintained under the supervision of persons knowledgeable in the limitations and potential life-endangering characteristics of supplied-air suits.

C. Advise employees of all areas and operations where exposure to DBCP could occur.

VIII. COMMON OPERATIONS

Common operations in which exposure to DBCP is likely to occur are: during its production; formulation into pesticides and fumigants; application of such pesticides and fumigants; and work in areas where such pesticides and fumigants have been applied, and processing of agricultural products containing residues of DBCP.

APPENDIX C—MEDICAL SURVEILLANCE GUIDELINES FOR DBCP

I. ROUTE OF ENTRY

Inhalation; skin absorption.

II. TOXICOLOGY

Recent data collected on workers involved in the manufacture and formulation of DBCP has shown that exposures to DBCP can cause sterility. This finding is supported by studies showing that DBCP causes sterility in animals. Chronic exposure to DBCP resulted in pronounced necrotic action on the parenchymatous organs (i.e., liver, kidney, spleen) and on the testicles of rats. Rats that were chronically exposed to DBCP also showed changes in the composition of the blood, showing low RBC, hemoglobin, and WBC, and high reticulocyte levels as well as functional hepatic disturbance, manifesting itself in a long prothrombin time. Reznik et al. noted a single dose of 100 mg produced profound depression of the nervous system of rats. Their condition gradually improved. Acute exposure also resulted in the destruction of the sex gland activity of male rats as well as causing changes in the estrous cycle in female rats. Animal studies have also associated DBCP with an increased incidence of carcinoma. Olson, et al. orally administered DBCP to rats and mice 5 times per week at experimentally predetermined maximally tolerated doses and at half those doses. As early as ten weeks after initiation of treatment, DBCP induced a high incidence of squamous cell carcinomas of the stomach with metastases in both species. DBCP also induced mammary adenocarcinomas in the female rats at both dose levels.

III. SIGNS AND SYMPTOMS

A. Inhalation: nausea, eye irritation, conjunctivitis, respiratory irritation, pulmonary congestion or edema, CNS depression with apathy, sluggishness, and ataxia.

B. Dermal: erythema or inflammation and dermatitis on repeated exposure.

IV. SPECIAL TESTS

1. Sperm count;
2. Serum Follicle Stimulating Hormone (FSH);
3. Serum Luteinizing Hormone (LH); and
4. Serum testosterone (males) or serum total estrogen (females).

NOTE.—The serum determinations in items 2, 3, and 4 should be performed by radioimmuno-assay techniques using NIH specific antigen or antigen preparations of equivalent sensitivity.

V. TREATMENT

Remove from exposure immediately, give oxygen or artificial resuscitation if indicated. Contaminated clothing and shoes should be removed immediately. Flush eyes and wash contaminated skin. If swallowed and the person is conscious, induce vomiting. Recovery from mild exposures is usually rapid and complete.

VI. SURVEILLANCE AND PREVENTIVE CONSIDERATIONS

A. Other considerations. DBCP can cause both acute and chronic effects. It is important that the physician become familiar with the operating conditions in which exposure to DBCP occurs. Those with respiratory disorders may not tolerate the wearing of negative pressure respirators.

B. Surveillance and screening. Medical histories and laboratory examinations are required for each employee subject to exposure to DBCP. The employer should screen employees for history of certain medical conditions (listed below) which might place the employee at increased risk from exposure.

1. Liver disease. The primary site of biotransformation and detoxification of DBCP is the liver. Liver dysfunctions likely to inhibit the conjugation reactions will tend to promote the toxic actions of DBCP. These precautions should be considered before exposing persons with impaired liver function to DBCP.

2. Renal disease. Because DBCP has been associated with injury to the kidney it is important that special consideration be given to those with possible impairment of renal function.

3. Skin disease. DBCP can penetrate the skin and can cause erythema on prolonged exposure. Persons with pre-existing skin disorders may be more susceptible to the effects of DBCP.

4. Blood dyscrasias. DBCP has been shown to decrease the content of erythrocytes, hemoglobin, and leukocytes in the blood, as well as increase the prothrombin time. Persons with existing blood disorders may be more susceptible to the effects of DBCP.

5. Reproductive disorders. Animal studies have associated DBCP with various effects on the reproductive organs. Among these effects are atrophy of the testicles and changes in the estrous cycle. Persons with pre-existing reproductive disorders may be at increased risk to these effects of DBCP.

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